UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

VOTE SHEET

DATE: September 12, 2001

TO: The Commission
Todd A. Stevenson, Acting Secretary

FROM: Michael S. Solender, General Counsel MSS
Stephen Lemberg, Assistant General Counsel SL
Lowell F. Martin, Attorney, GCRA (ext. 2217) LM

SUBJECT: Final PPPA Rules to Require Child-Resistant Packaging for Certain Household Products Containing Hydrocarbons

VOTE SHEET

The attached staff briefing package recommends that the Commission approve final rules to require child-resistant (CR) packaging for certain household products containing hydrocarbons. The rules, which are attached to the staff briefing package as Tab E, would apply prospectively to any such products packaged after the effective date, which if the Commission approves the final rules as drafted, would be one year after their publication in the Federal Register.

The draft final rules would require CR packaging pursuant to authority granted to the CPSC by the Poison Prevention Packaging Act of 1970, as amended, (PPPA). The new regulations would appear at 16 C.F.R. §§ 1700.14(a)(31) and (32).

The rules would apply to certain household products that contain ten percent (10%) or more hydrocarbons and have a viscosity of less than 100 Saybolt Universal Seconds (SUS) at 100 °F (covered products). For purposes of the rules, "hydrocarbons" are defined as those compounds, such as simple petroleum distillates, that consist solely of carbon and hydrogen. This is consistent with the proposed regulation (NPR) issued by the Commission for comment on January 3, 2000. 65 FR 93.

The provision at § 1700.14(a)(31) would apply to hazardous substances containing low-viscosity hydrocarbons. The provision at § 1700.14(a)(32) would apply to drugs and cosmetics containing low-viscosity hydrocarbons. This approach is due to the fact that the PPPA uses the enforcement mechanisms of the Federal Hazardous Substances Act (FHSA) for the former and the enforcement mechanisms of the Federal Food, Drug, and Cosmetics Act (FDCA) for the latter category of household products.

The NPR would have imposed the CR requirements on certain aerosols and pump and trigger sprayer packagings for covered products. These requirements are not imposed in the draft final rules.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial hb Date 9/13/01

CPSA 6 (b)(1) Cleared
No Mfrs/PrivLblrs 9/13/01
Products Identified
Excepted
Firms Notified

The staff recommends that the issues surrounding this aspect of the NPR be addressed in a future proceeding.

Please indicate your vote on the following options.

I. APPROVE THE FINAL RULES AS DRAFTED.

_____ _____
(Signature) (Date)

II. APPROVE THE FINAL RULES WITH THE FOLLOWING CHANGES (PLEASE SPECIFY).

_____

_____

_____

_____ _____
(Signature) (Date)

III. DO NOT APPROVE THE FINAL RULES AS DRAFTED

_____ _____
(Signature)
(Date)

IV. TAKE OTHER ACTION (PLEASE SPECIFY).

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment

Staff briefing package

BRIEFING PACKAGE

FINAL RULE TO REQUIRE SPECIAL PACKAGING FOR HYDROCARBONS OF LOW VISCOSITY

For Information Contact
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NOTE: This document has not been reviewed or accepted by the Commission.
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Excepted by [illegible]
Firms Notified.
Comments Processed.

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: SEP 12 2001

TO : The Commission
Todd Stevenson, Acting Secretary

THROUGH: Michael S. Solender, General Counsel MSS
Caroline Croft, Executive Director CC

FROM : Ronald L. Medford, Assistant Executive Director for Hazard Identification and Reduction RLM
Suzanne Barone, Ph.D. Project Manager for Poison Prevention, Directorate for Health Sciences

SUBJECT : Child-Resistant Packaging of Consumer Products that Contain Hydrocarbons of Low Viscosity

This memorandum addresses the comments received in response to 1) the proposed rule to require child-resistant packaging of products containing hydrocarbons of low viscosity and 2) the staff analysis of supplemental cosmetic exposure data. The staff recommendation that the Commission issue the rule is also included. A copy of a draft Final Rule prepared by the Office of the General Counsel is at Tab E.

BACKGROUND

The Poison Prevention Packaging Act (PPPA) was established to protect children from serious personal injury or illness resulting from handling, using, or ingesting hazardous household substances by requiring child-resistant packaging of these substances. The current regulations of the PPPA require child-resistant packaging of kindling and illuminating products, paint solvents, and furniture polish that contain hydrocarbons. However, as a chemical class, hydrocarbons are not currently required to be in child-resistant packaging. These chemicals are the primary ingredients in other consumer product categories that do not currently require child-resistant packaging, including cosmetics and automotive products. Direct aspiration into the lung, or aspiration during/following vomiting, of small amounts of the hydrocarbons can result in chemical pneumonia, pulmonary damage, and death. The viscosity of the hydrocarbon-containing product determines the potential toxicity. Viscosity is the measurement of the ability of liquid to flow. Liquids with high viscosity are thick or "syrupy" and liquids with low viscosity may be more "watery." Products with low viscosity pose a greater risk of aspiration into the lungs.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial MH Date 9/13/01

CPSA 6 (b)(1) Cleared
9/12/01
No Mfrs, Privates or Products Identified
Excepted
Firms Notified
Comments Processed.

On January 3, 2000, the CPSC issued a Notice of Proposed Rulemaking (NPR) proposing child-resistant packaging requirements for consumer products that contain hydrocarbons of low viscosity. A copy of the NPR is at Tab A.

The Commission proposed two separate rules, one for Federal Hazardous Substances Act (FHSA)-regulated products and the other for Food, Drug, and Cosmetic Act (FDCA)-regulated products. The proposed rules would require child-resistant packaging of prepackaged nonemulsion-type liquid household chemical products or drugs and cosmetics that contain 10 percent or more hydrocarbons[1] by weight with a viscosity of less than 100 Saybolt Universal seconds (SUS) at 100°F. (For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.)

The NPR outlined several packaging types that would be exempted from the rules including products packaged in aerosol cans, mechanical pumps, and trigger sprayers, that expel product in a mist. For mechanical pumps and trigger sprayers, the spray mechanism would be required to be permanently attached to the bottle or have a child-resistant attachment. However, if the mechanical pump or trigger sprayer expels product in a stream (either solely or as an option), the entire package including the pump mechanism would be required to be child-resistant. Aerosol products that form a stream by the addition of an extension tube inserted into the nozzle would be excluded from the packaging requirements if, without the extender, the product would be expelled as a mist.

Writing markers and ballpoint pens are exempted from full cautionary labeling requirements relating to ingestion toxicity under the FHSA if they meet certain specifications listed in the regulations. The Commission proposed that these products also be exempted from any child-resistant packaging requirements. In addition, the NPR proposed that cosmetics and other household substances containing 10 percent or more hydrocarbon by weight with a viscosity under 100 SUS, such as battery terminal cleaners, paint markers, and make-up removal pads, that do not have product free flowing from the packaging, be exempt from any child-resistant packaging requirements.

The NPR was sent to 375 trade associations and businesses believed to be involved with hydrocarbon-containing products. Seven individuals and groups submitted comments (Tab B). Most of the comments focused on which products should be subject to such a rule. Many of the comments reiterated comments that were previously received in response to the Advance Notice of Proposed Rulemaking (ANPR) and were addressed by the staff in the briefing package on the NPR.

[1] Hydrocarbons, for purposes of the proposed rules, are defined as compounds that consist solely of carbon and hydrogen.

Several commenters requested a test method to define "stream" for aerosol/pump/trigger sprayer products. The staff is not recommending that products that expel through an aerosol/trigger/pump packaging be included in this rule. At a later time, the staff will provide the Commission with a recommendation on a proposed method for distinguishing between aerosols/triggers/pumps that expel product in a stream that pose an aspiration risk and aerosols that expel product in a mist that would not pose an aspiration risk.

At the Commission meeting on December 3, 1999, Commissioner Gall requested that the staff develop a plan for the collection of additional data related to ingestion incidents involving mineral oil-based cosmetics. To this end, the staff recommended and the Commission approved the purchase of additional information on exposures to mineral oil-based cosmetics from the American Association of Poison Control Centers (AAPCC). These data were evaluated by the staff. In an April 11, 2001 Federal Register notice, the Commission announced to the public the availability of this information for comment (66 FR 18738). The comment period, which was extended at the request of the Cosmetic, Toiletry, and Fragrance Association (CTFA), ended on June 11, 2001. Four comments were received regarding the additional exposure data (Tab C).

The comments on the NPR and the additional data, the staff's responses, the findings required under the PPPA for issuance of a final rule, and the staff's recommendations are discussed below.

RESPONSE TO COMMENTS

Mechanical Pumps and Trigger Sprayers

Comment: One commenter (CP00-1-6) requested that the language of the proposed provision that would exempt pump- or trigger-actuated sprays that form a mist (16 CFR § 1700.14(a)(30)(i)) be clarified to be available only for pump sprays that have the pump unit permanently affixed to the container.

Response: The proposed exemption provision in the NPR reads," Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g. aerosols or pump-or trigger-actuated sprays) that expels the product solely as a mist." The phrase "the only non-child-resistant access to the contents is by a spray device" implicitly requires that the trigger or pump have either a permanent or a child-resistant attachment to the package.

The staff is not addressing the aerosol/pump/trigger exemption for products that expel in mist form in this briefing package. However, regardless of the status of the requirement for the spray mechanism itself to be child-resistant, products in trigger or pump sprayers that contain 10 percent or more hydrocarbons by weight with a viscosity of less than 100 SUS at 100°F would be required to have either a child-

resistant or permanent attachment to the product container if a hydrocarbon rule is issued. The draft final rule clarifies this requirement.

Comment: One commenter (CP00-1-4) suggested that senior testing not be required for assessing the removability of a trigger sprayer from the bottle because the child-resistant feature does not impact the usability of the product.

Response: Mechanical pumps and trigger sprayers have two points of access, through the spray mechanism and the attachment of the spray mechanism to the product container. Companies have two options concerning the attachment of the sprayer to the bottle. The sprayer can be either permanently attached or have a child-resistant attachment. A child-resistant attachment would be required if the container were to be refillable.

The senior test protocol at 16 CFR § 1700.20 provides that senior adults on the test panel open and close packaging properly according to the instructions found on the package. If the instructions for use are to operate the trigger, this feature should be tested (if the trigger mechanism is required to be child-resistant). If no instructions are found, activation of the trigger would still be considered the "normal usage" of the package. This agrees with the commenters' assertion. However, if there are instructions to refill the bottle or a refill is available for it, manufacturers should test to see if senior adults could remove and properly replace the trigger sprayer to refill the product container.

Single-Use Products

Comment: A comment (CP00-1-1) was received requesting that products intended for "total package use" not require child-resistant packaging. The commenter supported the addition of a labeling statement, and provided as an example, "Add entire contents to gasoline tank."

Response: This comment was addressed previously in the preamble of the NPR. The staff reiterates that any regulated product that is intended to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for the first opening, since the package must be effective for the life of the product. The manufacturer may use any packaging option that meets these requirements. In addition, the package should be labeled conspicuously with the direction that the entire contents should be used immediately upon opening. However, this type of labeling will not eliminate the requirement for child-resistant packaging beyond the first opening for products commonly used for more than one application. For example, an automotive additive would not necessarily be a "single-use-product" if only a portion of the contents was added to certain engine sizes.

Comment: Two commenters (CP00-1-4, 5) requested that language be added to the rule to address single-use products. They suggest, "Any regulated product that

is intended and likely to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening."

Response: The staff does not believe that additional language is necessary in the rule to address child-resistant packaging of single-use-products. The PPPA regulations clearly state that special packaging must continue to function for the number of openings and closings customary for its size and contents (16 CFR 1700.15(a)). One opening would be customary for a single-use product.

Turpentine

Comment: One commenter (CP00-1-7) requested that the requirement of the proposed rule be applied to turpentine with a viscosity level of less than 100 SUS at 100°F in addition to hydrocarbons.

Response: Liquid household products that contain 10 percent or more turpentine by weight now require child-resistant packaging. This rulemaking does not amend or supercede the turpentine child-resistant packaging regulation to include a viscosity requirement. While turpentine presents an aspiration hazard, turpentine is also readily absorbed following ingestion and systemic toxicity can result. The systemic toxicity associated with turpentine is different from the hazards of many hydrocarbons which have low systemic toxicity but a significant risk of chemical pneumonitis following aspiration. Turpentine, if ingested, is hazardous regardless of the viscosity. Therefore, the staff recommends retaining the current turpentine rule.

Writing Instruments

Comment: One commenter (CP00-1-7) stated a concern that if a marker contained a newly covered substance that was not exempted from FHSA labeling, the marker would require child-resistant packaging.

Response: In the NPR, the Commission proposed an exemption from child-resistant packaging for hydrocarbon-containing writing implements exempted from the FHSA labeling requirements (16 CFR 1500.83). In addition, the Commission proposed to exempt products from which the liquid could not flow freely. This would include paint markers or other such products not exempted from the FHSA regulations. Therefore, if a marker contained a "hydrocarbon" that is not specifically exempted under the FHSA labeling requirements, it would still not require child-resistant packaging as long as the hydrocarbon did not freely flow from the implement. However, the proposed exemption would not extend to substances beyond the "hydrocarbons" defined in the proposed rule. The hazard of different substances and their packaging would be examined separately. For example, pen-like markers that contain methacrylic acid were exempted from the child-resistant packaging requirements following review of specific hazard information (16 CFR 1700.14 (a)(29)). The staff does not recommend a "generic" PPPA

exemption for all marker-type packaging. Each type of substance should continue to be examined separately.

Effective Date

Comment: Two commenters (CP-00-1-4, 5) stated that an effective date of at least one year was appropriate. However, they requested that the Commission incorporate a procedure for companies to apply for a temporary stay of enforcement as was done previously in the rulemaking to revise the child-resistant packaging protocol test methods (60 FR 37710).

Response: The staff believes that one year is sufficient for manufacturers to adopt child-resistant packaging for hydrocarbon-containing products. The commenter provided no specific information that would demonstrate the need for additional time. The staff does not recommend that the Commission include a special procedure for the submission of requests for stays of enforcement as was done previously in the rulemaking to revise the child-resistant packaging protocol test methods. The technical difficulties involved with changing many different closure types, the large volume of products affected by that rule, and the availability of a large supply of child-resistant closures justified the incorporation of a special procedure. Those justifications do not hold for this current rulemaking. It should be noted that companies could request a stay of enforcement from the Commission or enforcement discretion from the Office of Compliance at any time on a case by case basis.

Comment: One commenter (CP00-1-2) requested that the effective date take into account the schedule for the development and marketing of suntan products, which have a long lead-time. In addition, the commenter stated that products not sold in one year may be held until the next season.

Response: The PPPA requires that no standard take effect later than one year from the date a rule is issued. The effective date applies only to products **packaged** on or after that date. Therefore suntan products packaged before the effective data but sold after the effective date would not have to comply. According to the commenter, the timing of bringing products to market is over a year. However, the schedule from product development to packaging is less than one year (according to the commenter, product lines are decided by December and production begins in August of the following year). The one-year effective date would thus allow ample time for suntan products subject to them to comply with the child-resistant packaging standards.

Additional Data on Mineral Oil-Based Cosmetics

The following comments were received in response to the staff analysis of additional information on exposures to mineral oil-based cosmetics from the brand name data purchased from the AAPCC. Two commenters submitted comments about

aerosol products. These comments will not be addressed in this briefing packaging since as was stated previously, the staff is not recommending that aerosols be included in this rule.

Comment: One commenter (CP-01-3-1) stated that it was important that CPSC identify all cosmetic products that would meet the criteria for requiring child-resistant packaging in order to protect children.

Response: Applicability of the proposed rule is based on the physical and chemical characteristics of the product and not its product category. That is, all products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F would require child-resistant packaging. The purpose of the rulemaking is to protect children from exposure to all products that contain low viscosity hydrocarbons that have the same potential for serious injury. The staff solicited information about products and categories of products that may fall under this rule to assess the scope of the rule and to determine if child-resistant packaging is available or can be developed for those classes of products. If the rule were issued as proposed, it would be the responsibility of the manufacturer of a product exhibiting the specified physical and chemical characteristics to comply with the rule.

Comment: One commenter (CP-01-3-4) stated that the TESS data and staff analyses are not valid for making the conclusion that mineral oil-containing cosmetics require child-resistant packaging.

Response: The TESS database is a specialized data collection system that contains information about calls to Poison Control Centers. The staff agrees that there are limitations to the TESS data. However, these data support the fact that children have access to cosmetic products that contain hydrocarbons. The cosmetic trade association agrees that the TESS data demonstrates that children access mineral oil-based cosmetics. If these products, or any others, have 10 percent or more hydrocarbons by weight with a viscosity less than 100 SUS at 100°F, serious injury could result from ingestion with accompanying aspiration. The TESS data simply confirm this.

Comment: One commenter (CP-01-3-4) stated that there is a low incidence of serious injuries and several of the deaths would not have been prevented by child-resistant packaging.

Response: The PPPA does not require a minimum number of deaths and serious injuries before the Commission can proceed with a child-resistant packaging rule. Rather, the PPPA requires that the Commission find that a substance is capable of causing serious injury or illness to young children that are exposed to it. The purpose of the human experience data is to demonstrate that children access products that may contain hydrocarbons and further validate the fact that aspiration of hydrocarbon-containing products with viscosities under 100 SUS at

100 °F can result in serious injury. The data presented demonstrates these points. However, the commenter states that the descriptions of the incidents do not support the conclusion that child-resistant packaging would have protected these children from death. The commenter attributes this either to the closure apparently being left off in one instance or to information being inconclusive in the other scenarios. While it is unknown if child-resistant packaging would have saved the lives of these children, the effectiveness of child-resistant packaging in reducing death is well documented. For prescription medicines and aspirin alone, CPSC estimates that the lives of over 900 children have been saved since child-resistant packaging was first required for these products. The commenter does not attempt to refute that aspiration of mineral oil-based cosmetics may be associated with serious injury. Requiring child-resistant packaging would limit access to these products by children in the future.

Comment: One commenter (CP-01-3-4) provided a calculation of relative risk and compared the risk of a baby oil fatality to the risk of death by other products and the risk levels used by the Department of Defense and the Federal Aviation Administration.

Response: The PPPA requires that the Commission find: 1) that a substance is capable of causing serious injury or illness to young children that are exposed to it and 2) that child-resistant packaging is technically feasible, practicable, and appropriate. The PPPA does not require a relative risk evaluation as a prerequisite to requiring child-resistant packaging.

ADDITIONAL DEATH INFORMATION

The staff has become aware of an additional death resulting from the aspiration of baby oil (010628HAA3357). According to the mother, the child, a 15-16 month-old who had a history of respiratory problems, ingested baby oil. The victim's twin brother opened the closed bottle of baby oil and gave it to the victim. The child was admitted to the hospital on the following day with breathing problems and died 29 days after the exposure. The death certificate lists respiratory failure due to acute respiratory distress syndrome (ARDS) and oil aspiration.

TECHNICAL FEASIBILITY, PRACTICABILITY, AND APPROPRIATENESS

Before issuing a regulation for hydrocarbon-containing products under the PPPA, the Commission must find that child-resistant packaging is technically feasible, practicable, and appropriate. Technical feasibility may be found when technology exists or can be readily developed to produce packaging that conforms to the standards described above. Practicability means that packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately

protect the integrity of the substance and not interfere with its intended storage or use.

The Commission made these findings preliminarily and proposed the rule. No comments were received regarding the technical aspects of child-resistant packaging. Therefore, the CPSC staff continues to conclude that the available data support the finding that it is technically feasible, practicable, and appropriate to produce special packaging for products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F.

EFFECTIVE DATE

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it finds that it is in the public interest to do so.

The Commission proposed a one-year effective date. Several comments were received regarding the effective date. The comments requested additional time for companies that may need it. However, no information was submitted to demonstrate that more than one year would be necessary to adopt child-resistant packaging.

The staff estimates that manufacturers can make all of the packaging changes within one year. Therefore, the staff continues to recommend an effective date of one year for this rulemaking. There is nothing to preclude an individual company from requesting relief from the Commission or the Office of Compliance if specific difficulties arise. The staff does not recommend the addition of a general procedure for stays of enforcement. No commenter provided specific information that would warrant instituting such a procedure.

ECONOMIC CONSIDERATIONS

A discussion of the economic considerations associated with requiring child-resistant packaging of household chemical products and cosmetics is at Tab D.

Before issuing a rule, in addition to complying with the requirements in the PPPA, the Commission must either assess the impact of a regulation on small businesses, or certify that there will not be a significant economic effect on a substantial number of small entities.

There are several reasons to expect that the rule will not have a significant economic effect on a substantial number of small entities. First, the incremental cost of CR packaging is low, usually in the range of $0.005 to $0.02 per package. These costs are generally passed on to the consumers and do not adversely

impact the manufacturers. Second, most manufactures of household, personal care, and cosmetic products tend to have diverse product lines that include product formulations that would not be covered by the regulations. Thus, the number of products that will require child-resistant packaging under this regulation may represent only a small proportion of any one firm's production. Finally, because the rule only applies to products packaged after the effective date, firms will be able to sell existing inventory of packaged product not in child-resistant containers. Since the effective date is one year after the Commission adopts the rule, firms should have sufficient time to find or develop child-resistant closures for their packages. Until, the effective date, firms can continue to package the products in non-child resistant packaging. Product packaged before the effective date may be distributed and sold after the effective date.

In the NPR, the Commission certified that the proposed rule if promulgated would not have a significant economic effect on a substantial number of small entities. The NPR was sent to 375 trade associations and companies believed to make products that contain hydrocarbons. The Commission did not receive any comments in response to the NPR that questioned the certification. Therefore, based on the available information, there is no evidence that the rule would have a significant economic impact on a substantial number of small entities.

ENVIRONMENTAL CONSIDERATIONS

A special packaging requirement will have little or no potential for affecting the human environment since the manufacture, use, and disposal of child-resistant packaging will present the same environmental effects as non child-resistant packaging.

OPTIONS

The following options are available to the Commission:

1. The Commission may issue rules requiring special packaging for household chemical and cosmetic products containing 10 percent hydrocarbon or more by weight and having a viscosity of less than 100 SUS at 100°F if the Commission finds that:

    i.) special packaging is required to protect young children from serious personal injury or illness from handling, using or ingesting the product; and

    ii.) special packaging is technically feasible, practicable, and appropriate.

2. The Commission may decide not to issue special packaging rules for hydrocarbon-containing products if it cannot make these findings.

RECOMMENDATION AND DISCUSSION

The staff recommends that the Commission issue the rules to require child-resistant packaging of products containing 10 percent or more hydrocarbons by weight and having a viscosity less than 100 SUS at 100°F.

The NPR was sent to 375 trade associations and companies. Few comments and information not addressed previously in the NPR were submitted. No new information was received that would change the staff's belief that rulemaking to require child-resistant packaging of hydrocarbon-containing products is needed. The toxicity of hydrocarbons is well defined and exposure is documented. The draft final rule would protect children from the same hazardous chemicals regardless of the product they are in.

Hydrocarbon-containing household chemical and cosmetic products with a viscosity level of less than 100 SUS at 100°F can cause serious injury or death if aspirated. For example, several brands of baby oil, a product intended for use on small children, are labeled with a warning as follows:

> "For external use only. Keep out of children's reach to avoid drinking and accidental inhalation, which can cause serious injury. Should breathing problems occur, consult a doctor immediately."

The possibility of serious injury documented on these manufacturers' product labels is precisely the finding the Commission must make to impose a child-resistant packaging requirement under the PPPA. The warning on baby oil is not specifically mandated by the FDA. Rather, the FDA's regulations at (21 CFR 740.1(a)) requires that, "the label of a cosmetic product bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." Thus, while the CTFA's comments assert that these products do not cause injury, the association members are labeling their products to warn about the serious injury that could result from ingestion or aspiration.

Although the CTFA does not agree with the staff about the need for child-resistant packaging for mineral oil-based cosmetics, they do agree that the data demonstrate that children access mineral oil-based cosmetics. The reported cases of serious injury and three deaths from baby oil, and a death from a hair moisturizer substantiate the potential hazard of these products.

It should also be clarified that the rule would not require child-resistant packaging of mineral oil-based cosmetics as a class. The rule would require child-resistant packaging only of hydrocarbon-containing consumer products possessing the physical and chemical characteristics that pose the requisite risk of

serious injury. The staff believes that sufficient information exists for the Commission to make the required findings and issue the rules.

No comments were received that questioned the technical findings or provided information that child-resistant packaging could not be adopted for a particular product. Therefore, the data support the necessary findings that child-resistant packaging is technically feasible, practicable, and appropriate for hydrocarbon-containing products.

The staff continues to recommend an effective date of one year. This will allow ample time to convert to child-resistant packaging and retire existing packaging stocks. While several commenters requested additional time, no information was submitted demonstrating that more time would be necessary. The staff does not recommend that the Commission issue a specific procedure for stays of enforcement as it had in the past with the revision of the child-resistant packaging test protocols.

We do not believe that these rules will have a significant effect on a substantial number of small businesses. We base this conclusion on our previous experience with child-resistant packaging costs and the lack of any comments from small businesses or others asserting any adverse effects.

TAB A

Applicability: Model A300 series airplanes, certificated in any category; except those on which Airbus Modification 04201 has been accomplished.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct corrosion of the fuselage skin panel, which could result in cracking and consequent reduced structural integrity of the airplane, accomplish the following:

Inspection

(a) Perform a one-time detailed visual inspection of the outer surface of the fuselage skin panel between fuselage frames FR39 and FR40, and between stringers 27 and 33, for corrosion; in accordance with Airbus Service Bulletin A300–53–0328, dated March 5, 1999. Perform the inspection at the applicable time specified in paragraph (a)(1), (a)(2), or (a)(3) of this AD. If any corrosion is found, prior to further flight, repair (*i.e.*, rework corroded areas, or repair or replace panels, as applicable) in accordance with the service bulletin, except as provided by paragraph (b) of this AD. Temporary repairs must be replaced with permanent repairs prior to accumulation of the life limits specified in the service bulletin.

(1) For airplanes for which the date of manufacture was less than 15 years before the effective date of this AD: Inspect within 18 months after the effective date of this AD.

(2) For airplanes for which the date of manufacture was at least 15 but less than 20 years before the effective date of this AD: Inspect within 12 months after the effective date of this AD.

(3) For airplanes for which the date of manufacture was 20 or more years before the effective date of this AD: Inspect within 6 months after the effective date of this AD.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

(b) Where Airbus Service Bulletin A300–53–0328, dated March 5, 1999, specifies that Airbus may be contacted for a repair, prior to further flight, replace the skin panel with a new or serviceable skin panel in accordance with the service bulletin.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directive 1999–209–281(B), dated May 19, 1999.

Issued in Renton, Washington, on December 27, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–34032 Filed 12–30–99; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Household Products Containing Hydrocarbons

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") has reason to believe that child-resistant packaging may be needed to protect children from serious illness or injury from products that contain low-viscosity hydrocarbons. This notice of proposed rulemaking ("NPR") proposes a rule under the Poison Prevention Packaging Act ("PPPA") that would require child-resistant packaging for many products that contain low-viscosity hydrocarbons. The Commission solicits written comments from interested persons.

DATES: The Commission must receive any comments in response to this notice by March 20, 2000.

ADDRESSES: Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207–0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–0800. Comments also may be filed by telefacsimile to (301)504–0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned "NPR for Hydrocarbons."

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0477, ext. 1196.

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act ("PPPA"), 15 U.S.C. 1471–1476, authorizes the U.S. Consumer Product Safety Commission ("CPSC") to require child-resistant packaging of hazardous household substances in appropriate cases. This notice proposes to require child-resistant packaging for certain low-viscosity hydrocarbon products. [1]

Direct aspiration into the lung, or aspiration during vomiting, of small amounts of petroleum distillates and other similar hydrocarbon solvents can result in chemical pneumonia, pulmonary damage, and death. Except in specific instances, the current regulations do not require that these solvents be in child-resistant packaging. However, these chemicals are the primary ingredients in many different consumer products to which children have access.

The viscosity of a hydrocarbon-containing product contributes to its potential toxicity. Viscosity is the measurement of the ability of liquid to flow. Liquids with high viscosities are thick or "syrupy," and liquids with low viscosities are more "watery." Products with low viscosity pose a greater risk of aspiration into the lungs.

Under regulations issued under the Federal Hazardous Substances Act ("FHSA"), the CPSC regulates the *labeling* of hazardous household substances containing 10 percent or more by weight petroleum distillates because these products may cause injury or illness if ingested. 16 CFR 1500.14. The PPPA regulations also require child-resistant packaging for some household products containing

[1] Statements by the Commissioners concerning this action are available from the Office of the Secretary.

petroleum distillates. 16 CFR 1700.14. Under these PPPA regulations, certain consumer products containing 10 percent or more by weight of petroleum distillates, and having viscosities less than 100 Saybolt Universal Seconds (SUS) at 100°F, are subject to child-resistant packaging standards. These PPPA-regulated products include prepackaged liquid kindling and illuminating preparations (*e.g.*, lighter fluid) (16 CFR 1700.14(a)(7)), prepackaged solvents for paint or other similar surface-coating materials (*e.g.*, paint thinners) (16 CFR 1700.14(a)(15)), and nonemulsion liquid furniture polish (16 CFR 1700.14(a)(2)).

Because hydrocarbons are not now regulated under the PPPA as a chemical class, many hydrocarbon-based consumer products are not required to be in child-resistant packaging. For example, cleaning solvents, automotive chemicals, shoe-care products, and cosmetics may contain large amounts of various hydrocarbons and are not required to be in child-resistant packaging. The existing child-resistant packaging standard requires child-resistant packaging of prepackaged kerosene for use as lamp fuel; however, a gun cleaning solvent that contains over 90 percent kerosene does not have to meet this requirement. Mineral spirits used as a paint solvent require child-resistant packaging, but spot removers containing 75 percent mineral spirits, and water repellents containing 95 percent mineral spirits, do not.

On February 26, 1997, the CPSC issued an advance notice of proposed rulemaking ("ANPR") to request comments and information about whether to require child-resistant packaging of hazardous household products that contain petroleum distillates and other hydrocarbons. 62 FR 8659. In addition to protecting children from serious injury, a rule requiring all hazardous products containing hydrocarbons to be subject to a child-resistant packaging standard would create a more consistent and comprehensive regulatory approach to child-resistant packaging for these products.

In the ANPR, the Commission solicited information on four specific issues: (1) The appropriate viscosity and/or percentage composition to be used as a threshold for requiring products that contain petroleum distillates to be in child-resistant packaging, (2) the inclusion of aerosol products in a requirement for the child-resistant packaging of products containing petroleum distillates or other hydrocarbons, (3) the scope of a rule to extend beyond petroleum distillates to include other hydrocarbons, such as benzene, toluene, xylene, pine oil, and limonene, and (4) the inclusion of restricted flow as an additional requirement for certain products, which would restrict the amount of product dispensed from an opened package during each attempt.

The Commission also solicited information on products that may be affected by such a rule, including chemical properties, users and use patterns, current packaging and labeling, economic information, and incident reports. The Commission extended the comment period until September 1, 1997, at the request of the Chemical Specialty Manufacturers Association ("CSMA") and the Cosmetic, Toiletry, and Fragrance Association ("CTFA"). 62 FR 22897 (April 28, 1997); 62 FR 38948 (July 21, 1997).

Staff also sent copies of the ANPR to 9 trade associations (representing over 1300 small and large companies) and to over 200 individual manufacturers of household products that may contain hydrocarbons.

B. The Scope of the Proposed Regulation

After reviewing the comments submitted in response to the ANPR, the Commission decided to propose a broad PPPA rule for household products that contain chemicals capable of causing chemical pneumonia and death following aspiration. The remainder of this Section B describes the scope and form of the proposed rule. Additional discussion of the rationale for these decisions is in later sections of this notice.

The proposed rule applies to prepackaged nonemulsion-type liquid household chemical products, including drugs and cosmetics, that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F. Hydrocarbons are defined as compounds that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

The definition of what is a "household substance" that can be regulated under the PPPA includes both a "hazardous substance" as defined in the FHSA and a "food, drug, or cosmetic" as those terms are defined in the Federal Food, Drug, and Cosmetic Act ("FDCA").[2] The enforcement of the PPPA with respect to hazardous substances relies on the misbranding and prohibited acts sections of the FHSA. The enforcement of child-resistant packaging requirements applicable to foods, drugs, or cosmetics relies on comparable provisions of the FDCA. Therefore, the Commission is issuing two separate rules, one for hazardous substances and one for drugs and cosmetics, to more closely associate a particular rule with the applicable enforcement mechanism. (Foods also are not covered under the proposed rule, because there are no data indicating a need for child-resistant packaging of food products.)

On November 19, 1998, the staff met with interested trade associations to discuss the scope of the potential rule. The emphasis of the meeting was to obtain information on various products or packaging types that should be included or excluded from the rule (Meeting log, December 3, 1998). Several trade associations submitted comments in response to the meeting. After considering these and the other comments, the Commission decided to exclude from the proposed rule products that do not present the risk of aspiration because of the way the product is dispensed. For example, aerosol products (*i.e.*, pressurized spray containers) that expel the product in a mist do not pose the risk of aspiration. The Commission also excluded products packaged in mechanical pumps and trigger sprayers that expel product in a mist, provided that the spray mechanism is either permanently attached to the bottle or has a child-resistant attachment. This makes the misted pump or trigger sprayer package equivalent to an aerosol can. If the aerosol can, mechanical pump, or trigger sprayer expels product in a stream (either solely or as an option), the spray mechanism and the means for affixing it to the reservoir container must be child-resistant. Aerosols and permanently affixed pumps or triggers may use a child-resistant overcap in lieu of a child-resistant actuating mechanism. Also, aerosol products that form a stream only when an extension

[2] A third category of products is included in the PPPA's definition of "household substance." This is "a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house." 15 U.S.C. 1471(2)(C). These fuels are not subject to the proposed rule because there is no reason to believe there is a need for child-resistant packaging of such products. (The Commission believes that products such as cans of kerosene sold to consumers likely are not "fuel * * * used in the heating * * * system of a house," even though some kerosene is used in portable heaters that may be used to heat a house. However, the Commission concludes that such products are "hazardous substance[s]" as defined in the FHSA.)

tube is inserted into the nozzle would be excluded from the packaging requirements if, without the tube, the product is expelled as a mist.

The FHSA regulation partially exempts small packages, minor hazards, and special circumstances from the FHSA's labeling requirements. 16 CFR 1500.83(a). Writing markers and ballpoint pens are exempt from full cautionary labeling requirements relating to toxicity if they meet certain specifications listed in the regulations. These products are also excluded from the proposed child-resistant packaging requirements due to the difficulty a child would have obtaining a toxic amount of fluid from these types of products. For the same reason, products that are packaged so their contents are not free-flowing, such as some battery terminal cleaners, paint markers, and make-up removal pads, are excluded from the proposed child-resistant packaging requirements.

The following section describes some of the products that may be subject to a child-resistant packaging standard if the proposed rule is ultimately issued.

C. Products That May Be Subject to the Proposed Rule

The proposed standard includes all household products as defined in the PPPA, unless exempted, that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100° F. This would impact many different classes of products that currently do not require child-resistant packaging. However, not all of the products within each category would require child-resistant packaging under the proposed rule, because many of those products do not meet the specified composition and viscosity criteria.

The staff identified several different automotive products that would require child-resistant packaging under the proposed rule. These products include carburetor cleaners, fuel injection cleaners, and some gasoline additives. Many of these products are intended for single use, and some are already in child-resistant packaging. Automotive lubricants, including motor oil and spray lubricants, for the most part will not be included in a proposed rule because motor oils have high viscosities and aerosols that expel the product as a mist are excluded from the proposed rule.

Other household chemicals subject to the proposed rule include spot removers and water repellents. Several of the spot removers that the staff identified were already in child-resistant packaging. However, the water repellents, especially those made for shoe care, are not. Cleaning products, including some floor and metal cleaners, would also be impacted by the proposed rule. Some miscellaneous sports-related products, including gun cleaners and archery arrow feather water repellents, contain hydrocarbons but were not in child-resistant packaging. Most writing instruments, including all markers and pens, are exempt from the proposed rule because they do not expel free-flowing hydrocarbons.

The current PPPA regulation requires child-resistant packaging of solvents for paint and other surface coatings, but child-resistant packaging of paint and varnishes themselves is not currently required. Most paints would not be included in the proposed rule because they contain insufficient hydrocarbons or are too viscous. However, some sealers, non-water-based varnishes, and stains may be covered. As discussed above, aerosol spray paints are not included in the proposed rule.

There are several categories of cosmetics that would be included in the proposed rule. In general, creams and lotions are not subject to the rule because they are either too viscous or are emulsions. Most baby oils, excluding lotions and gels, would be included in the proposal. The inclusion of other cosmetic products depends on their viscosities. Because of their composition and viscosities, some bath and suntan oils would be subject to the proposed rule, while others would not. Make-up removers and nail/cuticle conditioners may or may not require child-resistant packaging depending on hydrocarbon content, viscosity, and product form. Wipes and saturated pads are exempt.

These are the major product groups that have been identified. There may be other individual products that would require child-resistant packaging that have not been identified either by the staff or the comments on the ANPR.

The following section addresses the comments on the ANPR and further discusses the rationale for the scope of this rule.

D. The Commission's Response to Comments on the ANPR

The ANPR was sent to 221 trade associations and businesses believed to be involved with petroleum-distillate-containing products. Thirty individuals and groups submitted comments. Four commenters (comments numbered CP97–2–3, –11, –12, –18) supported the rule. Most of the other comments focused on which products should or should not be subject to such a rule.

1. *The scope of the rule.*

(a) *Aerosols. Comment:* Should a child-resistant packaging standard for low-viscosity petroleum distillates include aerosol products?

Response: There is insufficient evidence to demonstrate that there is a serious aspiration hazard from self-pressurized aerosols or spray mists that contain petroleum distillates. The commenters cited the results of animal studies conducted in the 1960's. The staff is not aware of new animal or human experience data that would change the conclusions that misted aerosols sprayed into the mouth do not pool in the mouth to result in aspiration. Accordingly, hydrocarbon-containing products in pressurized containers, that are expelled as a mist, are exempt from the proposed child-resistant packaging requirements.

Under the FHSA, special labeling related to toxicity is required for products containing 10 percent or more by weight of toluene, xylene, and petroleum distillates that may be aspirated into the lungs and result in chemical pneumonitis and death. For aerosol products, this special labeling under 16 CFR 1500.14(b)(3) related to the ingestion of hydrocarbon-containing products is required only when the contents are expelled as a stream. The industry requested that all hydrocarbon-containing aerosols be exempted from the child-resistant packaging requirements. However, a large volume delivered directly into the mouth could result in aspiration. Therefore, self-pressurized packages of hydrocarbon-containing products that can be dispensed in a coherent stream would be subject to the proposed child-resistant packaging requirements. Aerosol products that form a stream only when an extension tube is inserted into the nozzle would be excluded from the packaging requirements if, without the tube, the product is expelled as a mist. The CPSC laboratory staff determined that these products can be expelled through the extension tube at a rate of 1–2 ml/sec (Cobb, March 8, 1999). However, it is unlikely that a 2- or 3-year-old child would obtain a sufficient amount of fluid via this route to cause an aspiration hazard.

(b) *Viscosity. Issue:* What is the appropriate viscosity for requiring child-resistant packaging of products that contain hydrocarbons?

Response: After reviewing the submitted data and comments pertaining to viscosity, the Commission determined that the viscosity level where child-resistant packaging is not needed to protect children should remain at or above 100 SUS at 100° F. This is the viscosity below which the

FHSA regulations require precautionary labeling for ingestion of petroleum distillate-containing products and the PPPA regulations require child-resistant packaging of three product categories (furniture polish, paint solvents, and kindling and illuminating products).

Commenters and the medical literature agree that lower viscosities are associated with a greater risk of aspiration; however, there is no agreement about defining a "safe" upper level for viscosity. One published review article suggests that products with viscosities of 60 SUS or greater have low aspiration potential (Litovitz and Greene, 1988). Another recent review article recommends that only products with viscosities of less than 73.4 SUS require labels warning about the hazard of aspiration (Craan, 1996).

A draft revision to the Canadian Consumer Chemicals and Containers Regulations (CCCR) adopts 73.4 SUS and below for child-resistant packaging and cautionary labeling requirements. The current Canadian labeling and packaging requirements (CP97–2–23) use 70 SUS as the upper level.

There are concerns about this level because aspirations and resulting serious injury or death from pneumonitis and lipoid pneumonia have been documented with mineral oil-based products such as baby oil (Reyes De La Rocha et al, 1985, Perrot et al, 1992, IDI 97030HCC9033). These products have viscosities in the 60–75 SUS range.

Another comment asserted that the appropriate upper level based on the animal studies by Gerarde in the 1960's was 81 SUS (Klein, July 16, 1998, Gerarde, 1963). However, this level is too low, since it is at or close to the viscosity associated with aspiration of products that resulted in deaths and serious injuries. Therefore, the proposal includes products with viscosity levels less than 100 SUS at 100°F within the child-resistant packaging standard.

This would expand the current child-resistant packaging requirements from those limited to furniture polish, kindling and illuminating fluids, and paint solvents to include other product categories with similar ingredients and viscosities.

(c) *Hydrocarbons other than petroleum distillates. Issue.* Should a child-resistant packaging requirement include products that contain hydrocarbons other than petroleum distillates?

Response: Comments for and against including hydrocarbons other than petroleum distillates were received. Some commenters wanted to limit the rule to petroleum distillates. Other commenters suggested that compounds with the same risk of aspiration should be regulated regardless of their source. The Commission's decision falls between these two suggestions. The proposed rule includes products with solvents containing only hydrogen and carbon, commonly known as "hydrocarbons." The term "petroleum distillate" is archaic and refers to mixtures of hydrocarbons that are distilled from petroleum. There has been confusion about "petroleum distillates," especially regarding the aromatic hydrocarbons benzene, xylene, and toluene. The aromatics are components of some of the distillation fractions. However, the aromatics are not universally considered to be petroleum distillates because the toxicity of aromatics differs from the aliphatic chemicals. The Canadian standards currently do not include the aromatic hydrocarbons in their definition of petroleum distillates for cautionary labeling and child-resistant packaging (CP97–2–23).

In order for the proposed rule to be definite and comprehensive, the Commission proposes to not use the term "petroleum distillate" to define the scope of the rule. Instead the rule applies to those chemicals that contain only hydrogen and carbon. This will minimize confusion by making it clear that the aromatic hydrocarbons are intended to be included in a child-resistant packaging requirement. However, this does not change the FHSA's specific labeling requirements for the aromatic hydrocarbons. The Canadians have taken a similar approach. A draft revision to the Canadian standard eliminates the term "petroleum distillate" and lists chemical structures and classes to clarify what is included in the regulations.

Using the term hydrocarbon clarifies that the rulemaking will not be limited to petroleum-derived chemicals. It also eliminates one commenter's concern about confusion over whether the chemical limonene includes several different compounds. The recommended rule does not name individual compounds. Whether a product would require child-resistant packaging would depend on the total amount of hydrocarbon (by weight) and the product's viscosity.

The draft standard in Canada extends the requirements for labeling and packaging of aspiration hazards to include certain alcohols and ketones. The CPSC did not expand this rulemaking to include non-hydrocarbon chemicals, such as terpene alcohols, ketones, or alcohols, because of the diverse chemistry, toxicity, and uses of these chemicals. These non-hydrocarbon chemical classes should be evaluated separately for the need for child-resistant packaging.

(2) *Restricted flow.*

Issue: Should restricted flow be an additional requirement for certain products?

Response: Restricted flow is defined in 16 CFR 1700.15(d) as "* * * the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is shaken or squeezed once or when the container is otherwise activated once." Restricted flow is required in addition to child-resistant packaging for liquid furniture polish because many ingestions occurred while the product was in use and the top was already off. 16 CFR 1700.14(a)(2).

Restricted flow alone is not adequate to protect children, however. It does not prevent the child from directly accessing the product if the package is not child-resistant. Although restricted flow limits the amount of product a child can obtain each time the child attempts to ingest the product from the container, it does not limit the number of attempts the child may make.

None of the commenters identified a product class as needing restricted flow in addition to child-resistant packaging. Several commenters mentioned that restricted flow would impede the use of products where greater volumes are necessary for use. These commenters did not identify specific products.

A commenter requested that restricted flow be an alternative to child-resistant packaging for cosmetic products such as baby, body, and bath oils. The commenter stated that older adults might have difficulty opening the child-resistant packaging with hands wet from the bath or shower. The commenter stated that many of these products already had restricted flow.

The CPSC staff examined some cosmetic products with restricted orifices. None of these products met the PPPA's regulatory definition of restricted flow. The PPPA test procedures use adults aged 50 to 70 to determine adult-use-effectiveness for most packaging. This has led to the development of packaging systems that are easier for all adults to use properly (including resecuring the cap).

Furthermore, the rationale for restricted flow with furniture polish is that children would have access to the bottle *during* its use, in addition to when it was in storage. Therefore, the restricted-flow requirement is in addition to, not in lieu of, child-resistant packaging.

The Commission has not identified any specific product or product category where restricted flow would add additional protection to children. Therefore, the Commission is not requiring restricted flow for additional product categories. The requirement for restricted flow of liquid furniture polish currently in the PPPA regulations will remain.

(3) *Injury data.*

Comment: Several commenters (CP97–2–6, –15, –19–21) stated that the number of incidents and deaths were low and that child-resistant packaging was not justified.

Response: The CPSC believes that child-resistant packaging regulations should not be based solely on the number of incidents known to have occurred in the past. Before issuing a regulation under the PPPA, the Commission must find that "the degree or nature of the hazard to children in the availability of hydrocarbons, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance." 15 U.S.C. 1472(a)(1).

The ANPR presented ingestion data from various sources, including the CPSC's National Electronic Injury Surveillance System ("NEISS") and the Toxic Exposure Surveillance System ("TESS") maintained by the American Association of Poison Control Centers ("AAPCC"). The staff collected additional information on the NEISS cases where possible. The data collection was limited to product categories that may contain petroleum distillates and that are not currently required to be in child-resistant packaging. From these data, it can be shown that children do gain access to the categories of products that include some products that contain hydrocarbons.

The potential for aspiration and serious injury from these chemicals is well documented. Each time a child gains access to one of these products that is not in child-resistant packaging, there is the potential for ingestion, aspiration, pneumonitis, and death. Therefore, the Commission is proposing to require child-resistant packaging to protect children from accessing these products.

(4) *Packaging.*

(a) *Exempt aerosols. Comment:* One commenter (CP97–2–20 and 20a) stated that there are no currently available child-resistant/senior-friendly overcaps for aerosols. The commenter requested that the rule be clarified to say that aerosols are exempt from the senior-friendly requirements.

Response: The PPPA regulations exempt from the senior-friendly portion of the PPPA's requirements products that must be in aerosol form and products that require metal containers with reclosable metal closures. 16 CFR 1700.15(b)(2)(ii)(A). It is unnecessary to repeat this exemption specifically in a rule for hydrocarbon-containing products. However, the staff is aware of several child-resistant overcap designs that meet the senior-friendly requirements. The Commission will consider revisiting this issue in the future, but it is outside the scope of this rulemaking.

(b) *Exempt single-use products with heat seals. Comment:* Several commenters (CP97–2–20a and 7) requested that single use products with heat seals be exempted from the requirements.

Response: Any regulated product that is intended and likely to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening, since a toxic amount of the product will not remain after the product is opened and used. The manufacturer may use any packaging option that meets the PPPA requirements for the first opening. The CPSC has no data from tests of packages with thermal foil seals.

(5) *Miscellaneous.*

(a) *Education campaign. Comment:* The CSMA and several of its members (CP97–2–20, –15) requested that CPSC work with them and others on an education campaign to encourage consumers to read product labels and follow the directions and cautions. They request this because several of the incidents occurred while the product was not in its original container and, therefore, child-resistant packaging would not have prevented the incidents.

Response: The Commission agrees that education has value when used to communicate a safety message. Consumers need to be reminded to use child-resistant packaging properly. However, education does not replace the need for child-resistant packaging. Child-resistant packaging prevents ingestions and saves lives directly by creating a barrier between the child and the substance.

(b) *Parental responsibility. Comment:* One commenter (CP97–2–4) indicated that the issue was one of parental responsibility and that regulation was unnecessary.

Response: The issue of parental responsibility and child poisoning is not new. The Congressional Committee on Commerce dealt with this issue while drafting the Poison Prevention Packaging Act of 1970. The Committee report states, " * * * parental negligence is not the primary cause of poisonings. There are too many potentially hazardous products in the modern home to hope that all of them can be kept out of the reach of children." Child-resistant packaging creates a barrier between the child and the hazardous product when adult vigilance is insufficient. Therefore, the Commission proposes a rule to protect from ingesting products having the same potential aspiration hazard as other products that currently are required to have child-resistant packaging.

(c) *Labeling. Comment:* Comments (CP97–2–6, –25) were received stating that the labeling required under the FHSA was adequate to protect against the hazard and that child-resistant packaging was therefore unnecessary.

Response: Labels make important information available to the consumer; however, poisoning data demonstrate the inadequacy of labeling alone as an injury prevention strategy. The PPPA itself recognizes that FHSA labeling is not necessarily adequate to protect children by giving the Commission the ability to require child-resistant packaging for products that are toxic and thus already have to bear precautionary labeling including "Keep out of the reach of children." Human experience shows that it is unrealistic to expect labels to provide the same degree of protection as child-resistant packaging.

(d) *Garage storage. Comment:* A comment (CP97–2–1) stated that automotive products should not be included because they are stored in the garage and children do not have access to them.

(e) *Response:* The NEISS and TESS data included in the ANPR demonstrate that children do gain access to automotive products. These products should be in child-resistant packaging if they contain hydrocarbons and can be aspirated. Several companies voluntarily package their hydrocarbon-containing automotive products in child-resistant packaging.

(f) *Graffiti and "huffing." Comment:* One commenter (CP97–2–25) stated that child-resistant packaging of aerosol paints would not prevent vandalism or inhalant abuse (huffing).

Response: The Commission agrees with the commenter. The purpose of this rulemaking is to prevent children under 5 years of age from ingesting products that result in serious injury. To the extent that graffiti and huffing are done by older children, this

recommended rule would have little, if any, effect on these behaviors. To the extent the comment argues that aerosols should not be subject to the rule, most (those that expel the substance as a mist) are not.

(g) *Increased risk of injury to children. Comment:* The Cosmetics, Toiletries, and Fragrance Association (CP97–2–28) commented that requiring child-resistant packaging on baby oil could result in an increase in babies falling from changing tables or an increase in drowning incidents in bath tubs because parents would have to use both hands to open the package.

Response: According to the CTFA, about 70 percent of baby oil is used on adults and not babies. The comment assumes that adults who use baby oil on children now use only one hand to open and squirt out the product. The CTFA provided no evidence to support this. Containers for other baby products, including tubes or jars, often require two hands to open or use. The labeling on baby powder, for example, instructs parents to sprinkle the powder into their hands and then rub it on the baby. The comment also assumes that two hands are required to open all child-resistant packaging. In fact, however, there are child-resistant designs that can be opened with one hand. Further, parents can open the baby oil container ahead of time. The Commission finds it highly unlikely that baby oil in child-resistant packaging would increase the number of falls and drowning incidents.

E. Injury Data

The following section updates the ingestion data from household chemical products. The injury data reviewed at the time the ANPR was issued did not include cosmetic products. The CPSC staff has now reviewed ingestions of cosmetics product categories, including nail products, sunscreen and suntan preparations, bath oil and creams, lotions, and make-up, and the results are outlined below, along with a separate discussion of baby oil ingestion data.

1. *Household chemicals.*

The CPSC maintains the NEISS database of product-related injuries that were treated in hospital emergency rooms. The NEISS data are derived from a statistical sample of hospital emergency rooms in the United States. However, many ingestion exposures are handled by Poison Control Centers and are not treated in emergency rooms. The TESS database, which includes calls to poison control centers, is not a statistical sample, and the numbers of incidents cannot be used to make national estimates. The number of exposures reported in TESS represents a large percentage of the total calls to poison centers in a given year. However, the total annual number of ingestion incidents is likely to be greater than the actual number of cases reported in TESS.

The CPSC staff examined the NEISS data for ingestions by children under 5 years of age for the years 1995 through 1997. The product categories examined include workshop chemicals, adhesives, lubricants, metal polishes, automotive chemicals, paints, varnishes, and shellacs, spot removers, and automotive waxes, polishes, and cleaners. There were an estimated 6,800 ± 1,800 pediatric ingestions of these products seen in emergency rooms during the 3-year period.

In addition, the CPSC purchases TESS data for children under 5 years of age from the AAPCC each year. The data purchased include reported exposure calls. Informational calls are not purchased. The data do not include trade names. They are coded for broad product categories in a single code. The CPSC staff examined unintentional ingestion incidents from categories that contain products that may require child-resistant packaging under the regulation. These include carpet, upholstery, leather, or vinyl cleaners; automotive hydrocarbons; hydrocarbon spot removers; lubricants; other hydrocarbons; unknown hydrocarbons; other or unknown rust removers; floor wax, polish, or sealers; toluene or xylene adhesives; toluene or xylene; stains; and varnish and lacquers.

There were 44,781 ingestions of these products recorded in TESS for the years 1995–1997 (12,592, 16,433, and 15,756, respectively). Of these ingestions, 612 cases were also coded as aspirations. According to TESS guidelines, aspiration cases are automatically coded as ingestions in the TESS system. Of the aspiration cases, 122 resulted in "moderate" medical outcomes and 4 in "major" outcomes. No deaths from these product categories were reported during this period. A number of children had specific respiratory effects that were the direct result of the aspiration of the product. These include 31 cases of pneumonitis, 5 cases of respiratory depression, and 1 case of pulmonary edema.

Not all products in these categories contain hydrocarbons or have a viscosity of less than 100 SUS at 100 °F. For example, many of the adhesives and lubricants may have viscosities higher than 100 SUS. However, the data demonstrate that children do access the types of household chemical products that can contain hazardous levels of hydrocarbons. If these products contain hydrocarbons and have viscosities less than 100 SUS at 100 °F, children are at risk of aspiration and pneumonia. If the products are not hazardous hydrocarbon-containing products, the proposed rule does not affect them.

(2) *Cosmetics.*

NEISS does not have specific codes for cosmetic products. Therefore, NEISS data are not included in the review of cosmetics ingestions. CPSC staff examined TESS data for the years 1995–1997 for 4 general cosmetic categories known to have products that contain hydrocarbons. These include miscellaneous nail products, sunscreen and suntan preparations, bubble bath and bath oil, and creams, lotions, and make-up.

There were 74,042 ingestions of these products recorded in TESS for the years 1995–1997 (21,850, 25,514, and 26,678, respectively). Of these ingestions, 114 cases were coded as aspirations. Of the aspiration cases, 5 resulted in "moderate" medical outcomes, 2 in "major" outcomes, and 1 in a death (from baby oil). A number of children had specific respiratory effects that were the direct result of the aspiration of the product. These include 2 cases of pneumonitis, 2 cases of respiratory depression, and 1 case of respiratory arrest.

As stated previously, not all of the products in the categories contain hydrocarbons. For example, bath oil may contain hydrocarbons, but bubble bath is usually an aqueous detergent solution that would not be covered by the rule. In addition, not all of the hydrocarbon-containing products in each category would require child-resistant packaging because they have viscosities of 100 SUS or more at 100 °F. Creams and lotions that are emulsions would also not be included. For example, the staff collected a convenience sample of 5 different tanning products labeled as containing mineral oil and measured the viscosities and percentages by weight of hydrocarbons in these products. Of the five tanning products collected, one was an emulsion (lotion), two were tanning oils with viscosities in the 240 SUS range, and two were tanning oils with viscosities in the 65 SUS range. Only the latter two products would require child-resistant packaging under the proposed rule. This analysis cannot be extrapolated to identify the percentage of products in any category that may fall within the scope of the recommended rule. The example illustrates that there can be a range of viscosities in cosmetic products in the same category.

The cosmetic trade association argues that the aspiration hazard does not exist for cosmetic products. However, some companies warn about the possibility of serious injury on their labels, using the following: "For external use only. Keep out of children's reach to avoid drinking and accidental inhalation, which can cause serious injury. Should breathing problems occur, consult a doctor immediately." The FDA does not require this warning. The FDCA (21 CFR 740.1(a)) requires that "the label of a cosmetic product bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."

The TESS database documents aspirations from cosmetic products. In addition, the reported cases of serious injuries and a death from baby oil, regardless of the circumstances and whether child-resistant packaging would have prevented them, reinforce and support the potential hazard of these products. The viscosities of these products fall in the range where aspiration may be a hazard. The poisoning data indicate that children are accessing household chemicals and cosmetics that contain hydrocarbons. The potential for serious injury exists.

(3) *Baby oil.*

The Commission was specifically interested in incidents involving baby oil. A literature review documented one case of serious injury following aspiration of baby oil (Reyes de la Rocha, *et al.*, 1985). The CTFA's comment documented a similar case that resulted in permanent impairment of a child. The limited details that the CTFA supplied did not directly correlate with the published case. The two cases may not be the same. Moreover, there was a death of a child following ingestion of baby oil documented by the AAPCC (Litovitz *et al.*, 1997). The CPSC staff investigated the circumstances of the death (IDI 97030HCC9033); however, limited information was obtained. The child died 23 days after the ingestion. There was speculation that between 10 and 14 ounces of baby oil may have been ingested, although it was reported that the child was covered with baby oil. According to the AAPCC report a part of the cap was found in the child's stomach. The CTFA questioned the circumstances of this death. Nevertheless, the reported decrease in oxygen saturation and lung infiltration are consistent with aspiration pneumonitis.

The CPSC purchased data on exposures to baby oil by children under 5 years of age that AAPCC had compiled for the years 1996 and 1997. Over 2,500 incidents were reported during the 2-year period. Most of these cases involved ingestion. Most of the cases were managed at home. Several children exhibited symptoms and were admitted to the hospital. The CTFA also purchased these data and commented. It concluded that the data demonstrate the safety of baby oil.

The Commission is concerned about products such as baby oil that use lightweight mineral oil and have viscosities in the 60–99 SUS range. The authors of one report of a case involving baby oil conclude that "baby oil aspiration can be one of the causes of acute respiratory distress in children" (Reyes de la Rocha, 1985). They advocate that the latent danger of baby oil needs to be publicized since it appears that baby oil is not recognized as a cause of diffuse pneumonia and respiratory distress. This was demonstrated in a recent case documented in NEISS (981026HEP9021). An infant was accidentally given baby oil. According to the mother, she was told by the poison control center and the pediatrician that the child would have diarrhea. However, 3 days later the child was admitted to the hospital with pneumonia. While child-resistant packaging would not have prevented this ingestion, the case illustrates the potential dangers of the lightweight-mineral-oil-based products with viscosities under 100 SUS.

F. Technical Feasibility, Practicability, and Appropriateness

The PPPA standards for child-resistance and adult-use-effectiveness are defined in 16 CFR 1700.15 and are based on the results of human performance tests described in 16 CFR 1700.20. When tested according to the methods, 80 percent of tested children (41–52 months old) (based on 200 children) must not be able to access the package. In addition, most packages must be accessible to 90% of tested adults aged 50–70. The exceptions to this are products that require metal containers with metal closures or aerosols. These products must be accessible to 90% of adults tested aged 18 to 45 (16 CFR 1700.15(b)(2)(ii)). When this notice refers to child-resistance, it also means that the package meets the senior standard, unless otherwise specified.

Before issuing a regulation under the PPPA, the Commission must find that child-resistant packaging is technically feasible, practicable, and appropriate for the regulated products. 15 U.S.C. 1472(a)(2). "Technical feasibility" may be found when technology exists or can be developed to produce packaging that conforms to the standards described above. "Practicability" means that packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is "appropriate" when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use.

The CPSC staff assessed the packaging of a range of products that may be included in the rule. Based on that assessment, the Commission believes that child-resistant packaging is technically feasible, practicable, and appropriate for hydrocarbon-containing products. There are currently three product categories that contain petroleum-derived hydrocarbons and for which child-resistant packaging is required (16 CFR 1700.14(a)(2), (7), and (15)). Child-resistant packaging that meets the standards is available and compatible with these hydrocarbon-containing products. Many of the products that would be included in the recommended rule are similar in composition and use. This section will summarize technical information to support the findings for the variety of packaging types commonly used for hydrocarbon-containing products.

1. *Continuous threaded packaging.* Most packages that contain liquid products are currently sold with non-child-resistant continuous threaded (CT)(screw on) closures. These closures can be made of plastic or metal. This type of closure has been successfully modified to be child-resistant. There are several different types of child-resistant continuous threaded designs. The most common is the ASTM type IA closures. These are two-piece child-resistant closures that open by "pushing and turning." These types of closures are already being used on hydrocarbon-containing products, such as liquid furniture polish and mineral spirits. These and other types of continuous threaded closures are available from many different manufacturers. Stock closures are available and come in a variety of sizes, skirt lengths, and liner options. Plastic-on-metal closures are also available for products with solvents that may be incompatible with plastics.

Closures are also available that can accept brush applicators. Smaller sizes of these closures may have to be developed to accommodate the small bottles used for nail dryers and nail moisturizers. These packages are very similar to those used for nail primers that contain methacrylic acid, for which the Commission recently required child-

resistant packaging. 64 FR 32799 (June 18, 1999).

In most cases, the development of new closures or sizes will be unnecessary. However, modifications to the bottle neck finish and/or to the existing sorting and capping equipment may be necessary to change from non-child-resistant to child-resistant continuous threaded packaging.

(2) *Dispensing packaging (inserts and flip-tops).* The staff examined some cosmetic products that would be included in the recommended rule. Many baby oil, suntan oil, and bath oil products are currently packaged with dispensing capability. Several different packaging designs are being used, including restricted orifice plug inserts, flip-top dispensers, and finger pump dispensers.

The plug inserts and the flip caps both function by decreasing the orifice of the opening of the bottle. The plug insert fits flush with the opening of the bottle and does not interfere with the function of the closure. A child-resistant continuous threaded closure can replace the existing non-child-resistant closure as described above. The CPSC is not aware of any commercially available child-resistant flip-top closures for liquids. However, plug inserts with child-resistant closures can be substituted and serve the same function. Plug inserts are compatible with mineral-oil-based cosmetics because several of the cosmetic products currently use plug inserts. Manufacturers may have to change bottle neck finishes or buy plug insert equipment if they are not currently using the inserts.

(3) *Pump dispensers.* Some suntan oils are available with finger pumps. The Commission recently addressed the child-resistance of finger pumps during the minoxidil rulemaking. In a comment in that rulemaking, a manufacturer said that it could make a child-resistant finger pump. The finger sprayer for minoxidil has to be metered to deliver a specific dose. This is not the case for hydrocarbon-containing products; therefore, the development of a finger sprayer for these products should be less complicated.

Companies using finger pumps have other options. Other products in this category use plug inserts as described above. In addition, there are several child-resistant overcaps being developed specifically for pump sprayers.

Some of these alternatives are more complex than others and would require more time and money to complete.

(4) *Aerosols and trigger sprayers.* Any product meeting the proposed requirements that is in aerosol, pump, or trigger sprayer packaging, and that is expelled as a stream, must be in a child-resistant package. Child-resistant aerosol overcaps are available on the market. There are several designs that are also senior friendly. Since the overcaps do not come in contact with the products, compatibility of overcaps is not an issue.

For products that currently use a trigger sprayer, the CPSC is aware of a child-resistant trigger sprayer on the market and of several other designs under development. The Commission addressed the issue of child-resistant trigger sprayers during the fluoride rulemaking (63 FR 29949).

(5) *Metal container closures.* There are several designs, including snap caps and CT's, that are child-resistant and can be used with metal cans. These types of closures are currently being used on lighter fluids and some paint solvents. They are commercially available and compatible with hydrocarbons.

The CPSC concludes that the available data support the finding that it is technically feasible, practicable, and appropriate to produce special packaging for products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100 °F.

G. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it finds that it is in the public interest to do so. 15 U.S.C. 1471 note.

This rulemaking covers diverse groups of products with diverse packaging. Some of the packaging changes may be minimal, while others may be more extensive. For example, even though there are child-resistant packages readily available, changes from tool design to product-filling-line equipment may be required to replace some of the non-child-resistant packaging with various types of child-resistant packaging. In addition, there are multiple options available to manufacturers. Cost and consumer preference may play a role in determining which child-resistant feature is best suited to a product. Not all products in the same product category may take the same time to change to child-resistant packaging. However, the CPSC estimates that all of these packaging changes could be achieved within 1 year. Therefore, the Commission proposes an effective date of 1 year after publication of the final rule.

H. Economic Considerations

1. *Introduction.* Under the Regulatory Flexibility Act, the Commission must, when proposing a rule, either assess the impact of a regulation on small entities or certify that there will not be a significant economic effect on a substantial number of small entities. This section summarizes information about the potential impact on small businesses for both household chemical products and cosmetics and about the likely costs of packaging. After considering the available information, and the factors referred to in 15 U.S.C. 1472(b), the Commission concludes that the proposed rule is reasonable.

Three trade associations provided comments on economic issues: the Arts & Creative Materials Institute ("ACMI"); CSMA; and CTFA. The comments focused on (1) costs of child-resistant packaging for specific types of packaging or products and (2) the effects of the proposal on some manufacturers because of the uniqueness of their products. Only a few individual companies provided comments relating to economic issues.

Below, the Commission provides information on the products likely to contain hydrocarbons with characteristics subject to the proposal. Hydrocarbon-containing products regulated under the FHSA and FDCA are discussed separately.

2. *Hydrocarbon-containing products regulated under the FHSA.*

(a) *Market information.* Hydrocarbon-containing products for consumer use that are regulated under the FHSA appear in many product categories, including adhesives, air fresheners, all purpose cleaners, all purpose lubricants, art materials such as markers, automotive fluids and cleaners, metal cleaners and polishes, paint solvents, shoe polishes, spot removers, and water repellents. The products are dispensed in aerosol, gel, liquid and solid form.

Based on a survey of just a "few" of its 400 member companies, the CSMA reported that an average of about 80 million units of hydrocarbon-containing products are sold annually. The CSMA said its members consider product formulation to be confidential business information. One individual company reported annual average sales of about 2 million units of hydrocarbon-containing products in bottles and cans. However, no information on product categories or formulations was provided.

Table I provides 1996 dollar and unit sales for some categories of automotive and household cleaning products that

are likely to contain products formulated with hydrocarbons. However, the data do not reveal the share of the market attributable to hydrocarbon-containing products with characteristics that meet the criteria for the proposed rule or that are now packaged in child-resistant packaging.

TABLE 1.—SELECTED HOUSEHOLD PRODUCT CATEGORIES LIKELY TO CONTAIN PRODUCTS FORMULATED WITH HYDROCARBONS

Product category	$ Sales (millions)	Units [1] (millions)	Average retail price ($)
Auto treatments/ other auto fluids	276.9	164.6	1.68
Auto waxes/polishes	218.5	83.9	2.60
Furniture polish	212.0	54.0	3.93
Floor cleaners, wax, wax removers	109.7	47.6	2.30
Shoe/vinyl polish, cleaner/wax	31.0	13.1	2.37
Specialty cleaner, polish	48.4	9.5	5.09
Household lubricants	13.6	7.1	1.92

Source: Share Facts, Find/SVP, 1996
[1] Units are defined by Share Facts as 16 oz. equivalents

The Table 1 data do not include paints, coatings, or art materials. Although the National Paint and Coating Association ("NPCA"), which represents about half of the manufacturers or fillers of aerosol paints, noted that many aerosol paint formulas contain hydrocarbons, the association did not provide unit or dollar sales for these products. However, products packaged in aerosol containers that deliver a fine mist spray would not be subject to the proposed rule. Additionally, non-aerosol paints are not subject to the proposed rule because of their high viscosity.

The ACMI represents about 200 member companies that manufacture art and creative materials. ACMI surveyed its members and reported that less than 60 (exact number unknown) sell products that the proposal would cover. The association wrote that the products to which the proposal would apply are fairly specialized products used by adults (product types unspecified) in the art/hobby fields and that the products may not have a large sales volume. ACMI did not provide unit or dollar sales.

(b) *Packaging costs.* Neither the ACMI nor CSMA provided information on the potential costs of providing child-resistant packaging for their members' products. The ACMI reported that its members did not provide sufficient cost-related information to respond to the request. ACMI wrote that some member manufacturers are voluntarily using child-resistant packaging for certain hazardous products and that since members "tend to support the proposal and have products already in child-resistant packaging, it would not appear to raise major cost obstacles."

While neither ACMI nor CSMA provided information on potential costs, it might be noted that incremental costs for child-resistant packaging typically range from $0.005 to $0.02 per package. For products using a recently developed child-resistant trigger spray, incremental costs will amount to about $0.025 per package.

(c) *Small business effects.* The Commission does not know the universe of companies that would be affected by the proposed requirement. At least 1,500 large and small companies were notified of the proposal through trade associations and individual mailings. However, the responses to the ANPR provided no information indicating that small businesses would be significantly affected by the proposed child-resistant-packaging requirement. Additionally, there are several reasons to believe that the proposed rule would not have a significant impact on affected companies. Some manufacturers of household products that are subject to the proposal are currently providing child-resistant packaging. Manufacturers of household products typically have diverse product lines that also include product formulations that would not be included under the proposal. Thus, the number of products that would require child-resistant packaging may represent a small proportion of a firm's production. Finally, the firms would be able to exhaust existing inventory, since the rule would not apply to products packaged before the effective date.

Only two individual small companies commented on the packaging costs that would be incurred to convert their products to child-resistant packaging. While both indicated there would be an economic burden, neither provided specific cost information. The product of one company is packaged in an aerosol container and delivers a fine mist spray; the product of the other company is packaged in a tube with a restricted-flow moist-fiber applicator tip. Neither of these package types would be covered under the proposed rule; thus, the proposal will have no effect on these companies.

Based on the response to the ANPR, and the wide availability and relatively small incremental costs of child-resistant packaging, the Commission certifies that the proposed rule, if promulgated and as it relates to products regulated under the FHSA, will not have a significant economic effect on a substantial number of small entities.

3. *Hydrocarbon-containing products regulated under the FDCA.*

(a) *Market information.* Mineral oil, a hydrocarbon available in a wide range of viscosities, is used in a number of personal care products regulated under the FDCA. Products containing mineral oil and having a low viscosity, such as some baby oils, bath, massage, and sensual aroma oils, eye makeup removers, and nail care and sun care preparations, would also be covered under the proposed rule. While many of these products are typically sold separately, others are sold as part of a gift box that includes several items, for example, fragrant bath oil packaged with a soap and powder. The products may have aerosol, foam, gel, liquid, lotion, and solid formulations, and use a variety of delivery systems.

The CTFA, which represents about 275 manufacturers of cosmetic products, commented that most cosmetics product categories containing mineral oil are marketed in solid form and thus do not present an aspiration hazard. The association also noted that only a few of the cosmetics in liquid form would be subject to the contemplated child-resistant packaging requirement. This is because most exceed the viscosity limit and/or contain less than 10% hydrocarbons.

Many baby oil products are available in cream, lotion, and gel formulations.

The proposed rule will not affect these products because of their high viscosity. Similarly, the proposal will not affect many sun care products because of their high viscosities (creams, gels, lotions, solid sticks) or because they do not contain hydrocarbons.

In response to the ANPR, CTFA sent a survey to over 200 representatives of member companies and received only 15 completed surveys. CTFA reported that some companies returned the survey stating that they used no hydrocarbons, they were not currently marketing subject products, or their products were not for household use. In addition to products containing hydrocarbons, most manufacturers of cosmetics typically have extensive product lines and use various formulations without hydrocarbons. The association summarized member comments and provided information only by product category, without identifying brands or companies. There was no indication as to whether the responding companies were "small" or "large" businesses. Only manufacturers of baby oil provided market share and unit sales data in response to the survey. Based on these data, CPSC staff estimates the annual sales of baby oil at about 35 million units.

For all cosmetic product categories, *Drug Topics* (May 5, 1997) indicated that sales amounted to $2.9 billion and 911.5 million units in 1996. No breakout by type of product was given. However, the trade publication *Happi* (March 1996) reported that sun care products, a cosmetics category with some hydrocarbon-containing preparations, had $393.8 million in sales (almost 70 million units) in drug, food, and mass merchandise stores in 1995. However, *Happi* did not provide a breakout of the products that make up the sun care category, which includes sunscreens/sunblocks, self-tanners, and after-sun preparations.

(b) *Packaging costs.* Packaging for cosmetic products that may contain mineral oil currently includes finger press and pump dispensers, continuous threaded closures, flip tops with restricted orifices, finger spray pumps, and trigger sprays. Some nail care products are packaged with a plug insert restricted-neck fitting in the bottle's neck to remove excess product from the applicator brush.

According to a leading closure manufacturer, incremental costs for some types of child-resistant packaging that can be used for baby oil, sun care, and other mineral-oil-containing cosmetics are about $0.01 per unit (depending upon size, quantity ordered, and color). These package types include a commercially available package with a child-resistant closure and a restricted-neck fitting, and a dispensing cap with a flip top is under development. CTFA commented that a marketer of eye makeup remover reported the incremental cost for child-resistant packaging for the company's product would amount to 1.5 cents. Additionally, the incremental cost for a recently developed child-resistant trigger spray is about $0.025 per unit.

There is an unknown quantity of nail care products that the proposal may affect. Samples of mineral-oil-containing cuticle and nail oils CPSC staff examined were packaged with 13–20mm diameter neck finishes on bottles with built-in applicator brushes. They contain 0.4 to 1.0 oz of product. It may be necessary for some suppliers to change the closure and bottle finish in order to accommodate potentially available child-resistant packaging. There are at least two U.S.-based packaging manufacturers that could develop child-resistant closures with applicator brushes. No information is available regarding the incremental cost of such packaging.

In addition to the incremental cost of child-resistant packaging, manufacturers may also incur one-time start-up costs. Initial costs vary widely according to the product and to the extent of package redesign. CTFA provided estimates of one-time packaging costs based on the member survey noted earlier. The estimates for child-resistant packaging for baby oil, bath oil, and sunscreen products ranged from $163,000 to $1.5 million and, depending upon manufacturer, included research and development, new bottle molds, new custom-designed caps, and new tooling for product-filling lines. No specific information was provided to support these costs.

One manufacturer, providing comments independent of the CTFA, estimated the start-up costs for child-resistant packaging for baby oil at $122,000 for tooling and changing parts, assuming that only the closure changed and bottle shapes and sizes were not affected. The estimates for tooling and changing parts for child-resistant packaging for a tanning oil, moisture lotion, and bath oil ranged from $6,100 to $85,100.

(c) *Small business effects.* The concerns of some cosmetics manufacturers center on the need for custom-design packaging, especially for products with small markets, and on the effect of using child-resistant packaging on exports. As noted earlier, CTFA did not provide information regarding the identity of responding companies; thus, the Commission does not know if these manufacturers are small businesses. The high start-up cost estimates for custom-design child-resistant packaging were discussed above. One unidentified CTFA member commented that "packaging aesthetics is an integral element of cosmetics and [is] a key factor in packaging decisions and ultimately, consumer purchases." Several companies indicated that they would be forced to discontinue various products if child-resistant closures were required, because product sales would not support the costs of providing the packaging. Data regarding types of product, formulation, sales volume, and projected packaging costs were not provided.

A number of CTFA member companies also expressed concerns regarding exports of child-resistant packaged cosmetics. According to CTFA, packaging requirements for cosmetics would adversely impact global sales because "of a negative consumer perception in foreign countries about the safety of the U.S. product with a child-resistant closure versus the foreign competitor's product that is not child resistant." The association also commented that a foreign competitor's packaging cost could be lower than the U.S. product with a child-resistant closure and that consumers would buy the cheaper product in many cases. The association did not provide comparisons between foreign and domestic costs or data regarding the value of exports that the proposal may impact. The proposed rule does not require companies that export affected cosmetic products to use child-resistant packaging for their exports.

CTFA reports that one member company manufacturing a massage oil packaged with a continuous threaded closure and a restricted flow opening would drop the product rather than provide child-resistant packaging. According to CTFA, the product, selling at retail for $26 (6.7 oz) has low sales volume that does not make it "worth the investment to refit with special packaging." No estimate of the magnitude of the investment for child-resistant packaging was provided. Additionally, CTFA reported that one manufacturer of nail products said it would discontinue two products if child-resistant packaging were required. A second nail-product manufacturer anticipated that child-resistant packaging would cost several thousand dollars for custom cap retooling and result in a 40% increase (unstated dollar value) in ongoing packaging costs. The size of these businesses is unknown.

The Commission does not know the universe of companies that would be affected by the proposed requirement for child-resistant packaging for products regulated under the FDCA. The Commission requests that suppliers, especially small businesses and organizations representing small businesses, provide specific information about their products and the effect the proposed rule would have on them. The responses to the ANPR did not indicate that many small businesses would be affected. The wide availability and relatively small incremental costs of child-resistant packaging relative to the retail price of cosmetic products suggest that few firms should have a significant economic burden.

Based on the economic information available on the proposed rule affecting products regulated under the FDCA, the Commission certifies that the proposed rule, if promulgated, would not have a significant economic effect on a substantial number of small entities.

I. Preliminary Environmental Assessment

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has preliminarily assessed the possible environmental effects associated with the proposed packaging requirements for household products that contain hydrocarbons of low viscosity.

The Commission's regulations at 16 CFR 1021.5(c)(3) state that the rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of this proposed rule indicates that child-resistant packaging requirements for the production of marketers of low-viscosity hydrocarbon-containing products under the proposed rule will have no significant effects on the environment. The manufacture, use, and disposal of child-resistant closures will present the same environmental effects as do non-child-resistant closures.

J. Executive Orders

This proposed rule has been evaluated in accordance with Executive Order No. 13,083, and the rule raises no substantial federalism concerns.

Executive Order No. 12,988 requires agencies to state the preemptive effect, if any, to be given the regulation. The preemptive effects of these rules is established by Section 7 of the PPPA, which states:

> (a) * * * whenever a standard * * * under [the PPPA] applicable to a household substance is in effect, no State or political subdivision of a State shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard [and exemption, etc.].

15 U.S.C. 1476(a).

Subsection (b) of 15 U.S.C. 1476 provides a circumstance under which subsection (a) does not prevent the Federal Government or the government of any State or political subdivision of a State from establishing or continuing in effect a special packaging requirement applicable to a household substance for its own [governmental] use, and which is not identical to the standard applicable to the product under the PPPA. This occurs if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of injury than the consumer product safety standard.

Subsection (c) of 15 U.S.C. 1476 authorizes a State or a political subdivision of a State to request an exemption from the preemptive effect of a special packaging requirement. The Commission may grant such a request, by rule, where the State or political subdivision standard or regulation (1) would not cause the household substance to be in violation of the Federal standard, (2) provides a significantly higher degree of protection from the risk of injury than does the Federal standard and (3) does not unduly burden interstate commerce.

K. Trade Secret or Proprietary Information

Any person responding to this notice who believes that any information submitted is trade secret or proprietary should specifically identify the exact portions of the document claimed to be confidential. The Commission's staff will receive and handle such information confidentially and in accordance with section 6(a) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. 2055(a). Such information will not be placed in a public file and will not be made available to the public simply upon request. If the Commission receives a request for disclosure of the information or concludes that its disclosure is necessary to discharge the Commission's responsibilities, the Commission will inform the person who submitted the information and provide that person an opportunity to present additional information and views concerning the confidential nature of the information. 16 CFR 1015.18(b).

The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act ("FOIA"), 5 U.S.C. 552b; 18 U.S.C 1905; the Commission's procedural regulations at 16 CFR Part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If the Commission concludes that any part of information that has been submitted with a claim that the information is a trade secret or proprietary is disclosable, it will notify the person submitting the material in writing and provide at least 10 calendar days from the receipt of the letter for that person to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Reporting and recordkeeping requirements.

Effective date. The Commission proposes that the rule become effective 1 year after publication of the final rule. This period will allow manufacturers to make any changes in their production needed to comply with the standard without unduly delaying the safety benefits expected from the rule.

For the reasons set out in the preamble, the Commission proposes to amend 16 CFR 1700.14 as set forth below.

1. The authority citation for part 1700 continues to read as follows:

> **Authority:** 15 U.S.C. 1471–1476.
>
> Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. In § 1700.14 add new paragraphs (a)(30) and (a)(31) to read as follows:

§ 1700.14 Substance requiring special packaging.

(a) * * *

(30) *Hazardous substances containing low-viscosity hydrocarbons.* All prepackaged nonemulsion-type liquid household chemical products that are hazardous substances as defined in the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261(f)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100° F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the

contents is by a spray device (e.g., aerosols or pump-or trigger-actuated sprays) that expels the product solely as a mist. This exemption includes products that expel the product as a mist in their as-sold condition, but that can be modified by adding a tube to expel the product as a stream.

(ii) Writing markers and ballpoint pens exempted from labeling requirements under the FHSA by 16 CFR 1500.83.

(iii) Products from which the liquid cannot flow freely, including but not limited to paint markers and battery terminal cleaners. For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

(31) *Drugs and cosmetics containing low-viscosity hydrocarbons.* All prepackaged nonemulsion-type liquid household chemical products that are drugs or cosmetics as defined in the Federal Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. 321(a)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100° F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (*e.g.*, aerosols or pump- or trigger-actuated sprays) that expels the product solely as a mist. This exemption includes products that expel the product as a mist in their as-sold condition, but that can be modified by adding a tube to expel the product as a stream.

(ii) Products from which the liquid cannot flow freely, including but not limited to makeup removal pads. For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

* * * * *

Dated: December 23, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL177-1b; FRL-6506-4]

Approval and Promulgation of Implementation Plan: Illinois

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve an Illinois' State Implementation Plan (SIP) revision request affecting air permit rules, submitted on July 23, 1998. In the final rules section of this **Federal Register**, the EPA is approving the State's request as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. A detailed rationale for approving the State's request is set forth in the direct final rule. The direct final rule will become effective without further notice unless the Agency receives relevant adverse written comment on this action. Should the Agency receive such comment, it will publish a withdrawal of the final rule informing the public that the direct final rule will not take effect and such public comment received will be addressed in a subsequent final rule based on this proposed rule. If no adverse written comments are received, the direct final rule will take effect on the date stated in that document and no further activity will be taken on this action. EPA does not plan to institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments on this proposed rule must be received on or before February 2, 2000.

ADDRESSES: Written comments should be mailed to:

J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the State submittal are available for inspection at: Regulation Development Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Lauren Steele, Environmental Engineer, Permits and Grants Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-5069.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the final rules section of this **Federal Register**.

Dated: December 1, 1999.

Jo Lynn Traub,

Acting Regional Administrator, Region 5.

[FR Doc. 99-33625 Filed 12-30-99; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MT-001-0016b; FRL-6505-9]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for Montana; Revisions to the Missoula County Air Quality Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State implementation plan (SIP) revisions submitted by the Governor of Montana with a letter dated November 14, 1997. This submittal consists of several revisions to Missoula County Air Quality Control Program regulations, which were adopted by the Montana Board of Environmental Review (MBER) on October 31, 1997. These rules include regulations regarding general definitions, open burning, and criminal penalties. This submittal also includes revisions to regulations regarding national standards of performance for new stationary sources (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAPs), which will be handled separately.

In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

TAB B

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

CFSA 6 (b)(1) Cleared
No Mtgs/Pvt Lbls or
Products identified
Exceptions
Firms Notified
Comments Processed.
3/23/00

MEMORANDUM

DATE: March 22, 2000

TO : HS

Through: Sadye E. Dunn, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Proposed Rule on Household Products Containing Hydrocarbons, 65 FR 93, January 3, 2000

ATTACHED ARE COMMENTS ON THE CP 00-1

COMMENT	DATE	SIGNED BY	AFFILIATION
CP 00-1-1	1/18/00	Roger Tucker Director - Quality & Technology	Coastal Unilube, Inc. 44 North Second St. Suite 1200 Memphis, TN 38103
CP 00-1-2	3/14/00	Dennis Lott Exec. Director of Technical Affairs	Tanning Research Laboratories, Inc. P.O. Box 265111 Daytona Beach, FL 32126
CP 00-1-3	3/17/00	Students (3 classes)	Florida International University University Park Miami, FL 33199
CP 00-1-4	3/20/00	Brigid Klein Regulatory Counsel	Chemical Specialties Manufacturers Assoc. 1913 Eye Street, NW Washington, DC 20006
CP 00-1-5	3/20/00	S.E. Vredenburg	Pennzoil-Quaker State Company 700 Milam, P.O. Box 2967 Houston, TX 77252

Proposed Rule on Household Products Containing Hydrocarbons, 65 FR 93, January 3, 2000

CP 00-1-6	3/20/00	C. Beckley Assoc. General Counsel	The Comestic, Toiletry, & Fragrance Association 1101 17th St, NW Suite 300 Washington, DC 20036
CP 00-1-7	3/20/00	D. Fanning CAE, Exec. Vice President	The Art & Creative Materials Institute Incorp. 1280 Main St. P.O. Box 479 Hanson, MA 02341

TAB C

6445 62 6/6/01

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE : June 18, 2001

TO : HS

Through: Todd A. Stevenson, Acting Secretary

FROM : Martha Kosh

SUBJECT: Notice of Additional Hydrocarbon Data

ATTACHED ARE COMMENTS ON THE CP 01-3

COMMENT	DATE	SIGNED BY	AFFILIATION
CP 01-3-1	4/12/01	Michelle Lee	Bryn Mawr College C-1408 Bryn Mawr, PA 19010
CP 01-3-2	5/10/01	Heidi McAuliffe Counsel, Govern- ment Affairs	National Paint & Coatings Association, Inc. 1500 Rhode Island Ave, NW Washington, DC 20005
CP 01-3-3	5/11/01	Ann McCulloch Manager	Automotive Chemical Manufacturers Council 1225 New York Ave., NW Suite 300 Washington, DC 20005
CP 01-3-4	6/18/01	Catherine Beckley Assoc General Counsel	The Cosmetic, Toiletry, and Fragrance Association 1101 17th St, NW, Suite 300 Washington, DC 20036

TAB D

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: August 24, 2001

TO : Suzanne Barone
Project Manager
Hydrocarbons Project

THROUGH: Warren Prunella
Associate Executive Director
Directorate for Economic Analysis

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Economic Considerations Regarding the Final Rule to Require CR Packaging for Products Containing Low Viscosity Hydrocarbons.

The staff is recommending that the Consumer Product Safety Commission issue a final rule that would require child-resistant (CR) packaging for consumer products that are at least 10 percent hydrocarbon by weight and have viscosities of less than 100 Saybolt Universal Seconds (SUS) at 100° F. This rule would cover products in many categories including some automotive chemicals and cleaners, lubricants, paint solvents, and art materials. It would also cover some cosmetics and personal care products such as some mineral oils that may be used in baby oil and sun tan oil. Hydrocarbon-containing products packaged in aerosol containers or hydrocarbon products that are emulsions, such as creams or lotions, are not covered.

The Directorate for Economic Analysis prepared a report (published with the notice of proposed rulemaking (Federal Register vol. 65, no. 93)) on the products that are likely to be affected by, and the likely economic impacts of, the rule. Although several public comments were submitted in response to the notice, none of the comments provided new economic or market data related to the preliminary assessments of the potential impacts on small businesses or the environment. This memorandum presents the staff's final assessment of the potential impact of the rule on small businesses and the environment.

Small Business Effects

The universe of companies that would be affected by a rule requiring CR packaging for products (including some cosmetic and personal care products) that contain at least 10 percent hydrocarbons by weight and have viscosities of less than 100 SUS at 100° F is not known. There are at least several hundred manufacturers of household products and cosmetic and personal care products that may contain hydrocarbons that may be subject to the rule. Some of these may be

"small" according the criteria established by the Small Business Administration. However, there are several reasons to believe that the rule would not have a significant impact on a substantial number of small businesses.

First, the incremental cost of CR packaging is low, usually in the range of $0.005 to $0.02 per package. For some types of closures, such as a recently developed CR trigger spray, the incremental cost may be about $0.025 per package. These costs are generally passed on to the consumers and do not adversely impact the manufacturers. One trade association (representing manufacturers of art supplies) confirmed that the cost of CR closures is probably low and "would not appear to raise major cost obstacles." (Public Comment CP00-1-7)

Second, most manufacturers of household, personal care, and cosmetic products tend to have diverse product lines that include product formulations that would not be covered by the regulation. Thus, the number of products that will require CR packaging under this regulation may represent only a small proportion of any one firm's production.

Finally, because the rule only applies to products packaged after the effective date, firms will be able to sell any existing inventory of packaged product not in CR containers. Since the effective date is one year after the Commission adopts the rule, the firms should have sufficient time to find or develop CR closures for their packages. Until the effective date, firms can continue to package the products in non-CR packages. Products packaged before the effective may be distributed and sold after the effective date.

In the notice of proposed rulemaking the Commission certified that the proposed rule, if promulgated, would not have a significant economic effect on a substantial number of small entities. The Commission did not receive any public comments in response to the notice criticizing the certification. Therefore, based on the available information, there is no evidence that the rule would have a significant economic impact on a substantial number of small entities.

Environmental Review

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations, and CPSC procedures for environmental review, the Commission staff has reviewed the possible environmental effects associated with the rule to require certain low-viscosity hydrocarbon products to be in CR packages.

The Commission's regulations at 16 CFR 1021.5(c)(3) state that the rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Our analysis of the impact of the rule requiring special packaging for certain low-viscosity hydrocarbon products indicates that it will have little or no potential for affecting the human environment. This is because the manufacture, use, and disposal of CR closures present the same environmental effects as do non-CR closures.

TAB E

DRAFT

Billing Code 6355-01P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR 1700

Household Products Containing Hydrocarbons; Final Rules

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rules.

SUMMARY: These rules, promulgated under authority of the Poison Prevention Packaging Act (PPPA), require child-resistant (CR) packaging for certain products that contain low-viscosity hydrocarbons.[1] This requirement is intended to protect children under five years of age from serious injury associated with aspiration of hydrocarbon products. The requirement applies to certain prepackaged nonemulsion-type liquid household chemical products, including drugs and cosmetics, that contain ten (10) percent or more hydrocarbons by weight and have a viscosity of less than one hundred (100) Saybolt Universal Seconds (SUS) at 100° F (covered products). For purposes of these rules, hydrocarbons are defined as compounds that consist solely of carbon and hydrogen. For a product that contains multiple hydrocarbons, the total percentage of hydrocarbons in the

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[1] **[add fn re outcome of Commission vote]**

product is the sum of the percentages by weight of the individual hydrocarbon components.

DATE: These rules become effective _____ __, 2002 **[insert date that is 1 year after publication]**, and apply to covered products packaged on or after that date.

ADDRESS: Copies of documents relevant to this rulemaking can be requested from the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207-0001, (301) 504-0800, e-mail cpsc-os@cpsc.gov, or in person at Room 502, 4330 East-West Highway, Bethesda, Maryland.

FOR FURTHER INFORMATION CONTACT: Geri Smith, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0608, ext. 1160.

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act (PPPA), 15 U.S.C. 1471-1476, authorizes the U.S. Consumer Product Safety Commission (CPSC or Commission) to require child-resistant (CR) packaging of hazardous household substances in appropriate cases. These rules require CR packaging for certain low-viscosity hydrocarbon products.

Direct aspiration into the lung, or aspiration during vomiting, of small amounts of petroleum distillates and

other similar hydrocarbon solvents can result in chemical pneumonia, pulmonary damage, and death. These chemicals are the primary ingredients in a multitude of consumer products to which children have access.

The viscosity of a hydrocarbon-containing product contributes to its potential toxicity. Viscosity is the measurement of the ability of a liquid to flow. Liquids with high viscosities are thick or "syrupy." Liquids with low viscosities are more "watery." Products with low viscosity pose a greater risk of aspiration into the lungs.

Under regulations issued pursuant to the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1278, the CPSC regulates the labeling of hazardous household substances containing 10 percent or more by weight of petroleum distillate hydrocarbons because these products may cause injury or illness if ingested. 16 CFR 1500.14. The PPPA regulations in effect as of this date also require child-resistant packaging for certain household products containing petroleum distillates. 16 CFR 1700.14. Under these regulations, the specified consumer products containing 10 percent or more by weight of petroleum distillates, and having viscosities less than 100 Saybolt Universal Seconds (SUS) at 100°F, are subject to

child-resistant packaging standards. These PPPA-regulated products include prepackaged liquid kindling and illuminating preparations (e.g., lighter fluid) (16 CFR 1700.14(a)(7)), prepackaged solvents for paint or other similar surface-coating materials (e.g., paint thinners)(16 CFR 1700.14(a)(15)), and nonemulsion liquid furniture polish (16 CFR 1700.14(a)(2)).

Because hydrocarbons are not now regulated as a chemical class under the PPPA, many other hydrocarbon-based consumer products are not required to be in child-resistant packaging. Cleaning solvents, automotive chemicals, shoe-care products, and cosmetics may contain large amounts of various hydrocarbons and are not required to be in child-resistant packaging. For example, an existing child-resistant packaging standard requires child-resistant packaging of prepackaged kerosene for use as lamp fuel.

However, a gun cleaning solvent that contains over 90 percent kerosene does not have to meet this requirement. Mineral spirits used as a paint solvent require child-resistant packaging, but spot removers containing 75 percent mineral spirits, and water repellents containing 95 percent mineral spirits, do not.

On January 3, 2000, the CPSC issued a Notice of Proposed Rulemaking (NPR) proposing CR packaging requirements for consumer products that contain hydrocarbons of low viscosity. 65 FR 93.

The Commission proposed two discrete rules, one for products regulated under the FHSA and the other for products regulated under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301-397. The proposed rules would require CR packaging of prepackaged nonemulsion-type liquid household chemical products or drugs and cosmetics that contain 10 percent or more hydrocarbons[2] by weight and have a viscosity of less than 100 SUS at 100°F. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

The NPR outlined several packaging types that would be exempted from the rules. These included products packaged in aerosol cans, and mechanical pumps or trigger sprayers, provided the aerosol, mechanical pump, or trigger sprayer expelled the product as a mist. For mechanical pumps and trigger sprayers, the spray mechanism would be required to

[2] Hydrocarbons are defined for purposes of these rules as compounds that consist solely of carbon and hydrogen.

be permanently attached to the bottle or have a CR attachment. However, if the mechanical pump or trigger sprayer expelled product as a stream (either solely or as an option), the entire package including the pump mechanism would have been required to be CR. Aerosol products that formed a stream by the addition of an extension tube inserted into the nozzle would have been excluded from the packaging requirements if, without the extension tube, the product would be expelled as a mist.

Writing markers and ballpoint pens are exempted from full cautionary labeling requirements under the FHSA relating to ingestion toxicity if they meet certain specifications prescribed by regulation. 16 CFR 1500.83. The Commission proposed that these products also be exempted from CR packaging requirements. In addition, the NPR proposed that cosmetics and other household substances, such as battery terminal cleaners, paint markers, and make-up removal pads, that do not have product free flowing from the packaging, be excluded from the CR packaging requirements, even if they contained 10 percent or more hydrocarbons by weight and have a viscosity under 100 SUS.

The NPR was sent to 375 trade associations and businesses believed to be involved with hydrocarbon-

containing products. Seven individuals and groups submitted comments. Most of the comments focused on which products should be subject to the rules. Many of them reiterated comments that were previously submitted in response to the advance notice of proposed rulemaking (ANPR) and addressed in the NPR.

Several commenters requested a test method to define "stream" for aerosol and pump and trigger spray products. Aerosols and the discharge from pump and trigger spray mechanisms are not subject to the final rules being issued today. The CPSC expects to address the "stream" vs. "mist" issue in a subsequent proceeding.

At the Commission meeting on December 3, 1999, Commissioner Gall requested that the CPSC staff develop a plan for the collection of additional data related to ingestion incidents involving mineral oil-based cosmetics. To this end, the Commission approved the purchase from the American Association of Poison Control Centers (AAPCC) of additional information on exposures to mineral oil-based cosmetics. These data were evaluated by the CPSC staff. In an April 11, 2001 supplemental Federal Register notice of data availability, the Commission provided an opportunity for the public to comment on this information. 66 FR 18738.

The comment period, which was extended at the request of the Cosmetic, Toiletry, and Fragrance Association (CTFA), ended on June 11, 2001. Four comments were received in response to the notice.

The comments on the NPR and the additional data, the CPSC's responses, the scope of these final rules, and the Commission findings required under the PPPA for issuance of the rules, are discussed below.

B. Response to Comments on the NPR

1. Mechanical Pumps and Trigger Sprayers

Comment: One commenter (CP00-1-6) requested that the language of the proposed provision that would exempt pump- or trigger-actuated sprays that form a mist be modified to state clearly that the exemption is only available for pump/trigger sprays that have the pumping unit permanently affixed to the product container.

Response: The exemption provision proposed in the NPR read, "Products in packages in which the only non-CR access to the contents is by a spray device (e.g. aerosols or pump-or trigger-actuated sprays) that expels the product solely as a mist." The phrase "the only non-child-resistant access to the contents is by a spray device" implicitly requires that

the trigger or pump have either a permanent or a CR attachment to the package.

The final rules being issued today do not cover aerosols or pump or trigger spray mechanisms. However, irrespective of the absence from the final rules of a requirement for the aerosol or pump/trigger spray mechanism itself to be child-resistant, products in trigger or pump sprayers that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F must still have either a CR or permanent attachment to the product container. The language of the final rules clarifies this requirement.

Comment: One commenter (CP00-1-4) suggested that senior testing should not be required for assessing the removability of a trigger sprayer from the product container because a senior does not need to remove the trigger mechanism to use the product.

Response: Mechanical pumps and trigger sprayers have two routes of access to the package contents -- via the spray mechanism and via the attachment of the spray mechanism to the product container. Companies have two options concerning the attachment of the sprayer to the container. The sprayer can be either permanently attached or have a CR

attachment. A CR attachment is required if the container is refillable.

The senior test protocol at 16 CFR 1700.20 directs that the senior adults on the test panel open and close the packaging properly according to the instructions found on the package. If the instructions for use are to operate the trigger, this feature should be tested (for a product where the trigger mechanism is required to be child-resistant). If no instructions are found, activation of the trigger would still be considered the "normal usage" of the package. This approach is consistent with the commenter's view. However, if the trigger mechanism itself is removable, manufacturers would need to test to see if senior adults could remove and properly replace the trigger sprayer mechanism onto the product container.

2. Single-Use Products

Comment: A comment (CP00-1-1) was received requesting that products intended for "total package use" not require CR packaging. The commenter supported the addition of a labeling statement, and provided as an example, "Add entire contents to gasoline tank."

Response: This comment was addressed previously in the preamble of the NPR. CPSC reiterates that any regulated

product that is intended to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for the first opening, since regulations require that the CR packaging be effective for the life of the product. However, for example, an automotive additive would not necessarily be a "single-use-product" if only a portion of the contents were to be added to certain engine sizes.

Comment: Two commenters (CP00-1-4, 5) requested that language be added to the rules to address single-use products. They suggested, "Any regulated product that is intended and likely to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening."

Response: Additional language is not necessary in the rules to address CR packaging of single-use-products. The regulation clearly states that special packaging must continue to function for the number of openings and closings customary for its size and contents. 16 CFR 1700.15(a). One opening would be customary for a single-use product.

3. Turpentine

Comment: One commenter (CP00-1-7) requested that the CR packaging requirement of the proposed rules be applied to

turpentine with a viscosity level of less than 100 SUS at 100°F in addition to hydrocarbons.

Response: While turpentine presents an aspiration hazard, turpentine is also readily absorbed following ingestion and systemic toxicity can result. The systemic toxicity associated with turpentine is different from the hazards of many hydrocarbons which have low systemic toxicity but a significant risk of chemical pneumonitis following aspiration. Turpentine, if ingested, is hazardous regardless of the viscosity. Liquid household products that contain 10 percent or more turpentine by weight now require CR packaging. 16 CFR 1700.14(a)(6). These final rules do not amend or supersede the turpentine CR packaging regulation, which remains applicable without regard to the viscosity of the turpentine product.

4. Writing Instruments

Comment: One commenter (CP00-1-7) stated a concern that if a marker contained a substance newly covered by these final rules that was not exempted from FHSA labeling, the marker would require CR packaging.

Response: In the NPR, the Commission proposed an exemption from CR packaging for hydrocarbon-containing writing implements exempted from the FHSA labeling requirements. 16

CFR 1500.83. In addition, the Commission proposed to exempt products from which the liquid could not flow freely. This would include paint markers or other such products not exempted from the FHSA labeling regulations. Therefore, under the rules as proposed, if a marker contained a "hydrocarbon" not specifically exempted from the FHSA labeling requirements, it would still not require CR packaging if the hydrocarbon did not freely flow from the implement. However, the proposed exemption would not extend to substances beyond "hydrocarbons" as defined in the proposed rule. The final rules issued today adopt these exemption provisions.

5. *Effective Date*

Comment: Two commenters (CP-00-1-4, 5) stated that an effective date of at least one year was appropriate. The commenters requested that the Commission incorporate a procedure for companies to apply for a temporary stay of enforcement as was done previously in the CPSC rulemaking to revise the CR packaging protocol test methods. 60 FR 37710.

Response: The Commission believes that one year is sufficient for manufacturers to adopt CR packaging for hydrocarbon-containing products. The commenter provided no specific information that would demonstrate the need for

additional time. The Commission is not including a special procedure for the submission of requests for stays of enforcement as was done in the previous CPSC rulemaking to revise the CR packaging protocol test methods. The large volume of products affected by that rule, the technical difficulties involved with changing many different closure types, and the availability of a large supply of CR closures justified the incorporation of a special procedure. This rulemaking does not involve those considerations. However, a company can request a stay of enforcement from the Commission or enforcement discretion from the CPSC Office of Compliance at any time on a case by case basis.

Comment: One commenter (CP00-1-2) requested that the effective date take into account the schedule for the development and marketing of suntan products, which have a long lead-time. In addition, the commenter stated that products not sold in one season may be held until the next year's season.

Response: The PPPA requires that no standard take effect later than one year from the date a rule is issued. 15 U.S.C. 1471n. However, the standard applies only to products packaged on or after the effective date. Therefore, suntan products packaged before the effective

date but sold thereafter are not subject to the rules. According to the commenter, the timing of bringing products to market is over a year. However, the schedule from product development to packaging described in the commenter's submission is less than one year. (Product lines are decided by December and production of those lines begins in August of the following year.) The one-year effective date thus allows ample time for suntan products subject to these final rules to comply with the CR packaging requirement.

6. Additional Data on Mineral Oil-Based Cosmetics

The following comments were received in response to the Federal Register notice providing a public comment period on the CPSC staff analysis of the additional brand name data purchased from the AAPCC on exposures to mineral oil-based cosmetics. 66 FR 18738-40 (April 11, 2001). Also, two commenters submitted comments about aerosol products. Since, as was stated previously, the final rules issued today do not apply to aerosols, these comments are not addressed here.

Comment: One commenter (CP-01-3-1) stated that it was important that the CPSC identify all cosmetic products that would meet the criteria for requiring CR packaging.

Response: Applicability of the proposed rules is based on the physical and chemical characteristics of the product, not its product category. That is, any product that contains 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F is required to be in CR packaging, unless otherwise exempted. The purpose of the rules promulgated today is to protect children from exposure to any product that contains low viscosity hydrocarbons that have the potential for serious injury. The CPSC staff solicited information about products and categories of products that might be subject to the rules to assess their scope and to determine if CR packaging is available or can be developed for those types of products. Under these final rules, it is the responsibility of the packager of a product exhibiting the specified physical and chemical characteristics to comply. What category the product type happens to fall within is irrelevant.

Comment: One commenter (CP-01-3-4) stated that the TESS data and staff analyses are not valid for making the conclusion that mineral oil-containing cosmetics require CR packaging.

Response: The TESS database is a specialized data collection system that contains information about calls to Poison Control Centers. The staff agrees that there are

limitations to the TESS data. However, these data support the fact that children do access cosmetic products that contain hydrocarbons. See, 66 FR 18739 (April 11, 2001)(The CPSC staff analysis of the additional data on mineral oil-based cosmetics shows at least 1,460 cases of access). CTFA in its comment concurs that the data demonstrate that children access mineral oil-based cosmetics. If these products, or any others, have 10 percent or more hydrocarbons by weight with a viscosity less than 100 SUS at 100°F, serious injury could result from ingestion with accompanying aspiration. The TESS data simply further confirm this.

Comment: One commenter (CP-01-3-4) stated that the data show a low incidence of serious injuries and that several of the deaths would not have been prevented by CR packaging.

Response: The PPPA does not require a minimum number of deaths and serious injuries before the Commission can proceed with a child-resistant packaging rule. Rather, the PPPA requires that the Commission find that a substance is capable of causing serious injury or illness to young children that are exposed to it. The purpose of the human experience data is to demonstrate that children access products that may contain hydrocarbons and to further

validate the fact that aspiration of hydrocarbon-containing products with viscosities under 100 SUS at 100 °F can result in serious injury. The data presented demonstrate these points. 66 FR 18739. However, the commenter states that the descriptions of the incidents do not support the conclusion that child-resistant packaging would have protected these children from death. The commenter attributes this either to the closure apparently being left off in one instance or to information being inconclusive in the other scenarios. While it is unknown if child-resistant packaging would have saved the lives of these children, the effectiveness of child-resistant packaging in reducing deaths is well documented. For prescription medicines and aspirin alone, CPSC estimates that the lives of over 900 children have been saved since child-resistant packaging was first required for these products. The commenter does not attempt to refute that aspiration of mineral oil-based cosmetics may be associated with serious injury. Requiring child-resistant packaging would limit access to these products by children in the future.

Comment: One commenter (CP-01-3-4) provided a calculation of relative risk and compared the risk of a baby oil fatality to the risk of death by other products and the risk levels

apparently used by the Department of Defense and the Federal Aviation Administration.

Response: The PPPA requires that the Commission find: 1) that a substance is capable of causing serious injury or illness to young children that are exposed to it and 2) that CR packaging is technically feasible, practicable, and appropriate. 15 U.S.C. 1472(a). The PPPA does not require a relative risk evaluation as a prerequisite to requiring CR packaging.

C. Additional Death

CPSC staff has become aware of an additional death resulting from aspiration of baby oil ((010628HAA3357). The victim's twin brother opened the closed bottle of baby oil and gave it to the victim. According to the mother, the child, a 15-16 month-old who had a history of respiratory problems, then ingested baby oil. The child was admitted to the hospital on the following day with breathing problems and died 29 days after the exposure. The death certificate lists respiratory failure due to acute respiratory distress syndrome (ARDS) and oil aspiration.

D. The Scope of the Regulations

After reviewing the comments submitted in response to the NPR and the supplemental notice of data availability, the Commission has decided to issue final PPPA rules for household products that contain hydrocarbon chemicals capable of causing chemical pneumonia and death following aspiration. The remainder of this section describes the scope and form of the final rules.

The rules apply to prepackaged nonemulsion-type liquid household chemical products, including drugs and cosmetics, that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F. Hydrocarbons are defined as compounds that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

The final rules exclude aerosol products (i.e., pressurized spray containers). The rules also exclude products packaged in mechanical pumps and trigger sprayers, provided that the spray mechanism is either permanently attached to the product container or has a child-resistant attachment. Potential coverage of aerosols, pump and

trigger sprayers will be addressed separately in a future proceeding.

The definition of what is a "household substance" that can be regulated under the PPPA includes, *inter alia*, both a "hazardous substance" as defined in the FHSA and a "food, drug, or cosmetic" as those terms are defined in the Federal Food, Drug, and Cosmetic Act (FDCA). Enforcement of the PPPA with respect to hazardous substances is accomplished using the misbranding and prohibited acts sections of the FHSA. Enforcement of child-resistant packaging requirements applicable to foods, drugs, or cosmetics relies on comparable provisions of the FDCA. Therefore, the Commission is issuing two discrete rules, one for hazardous substances and one for drugs and cosmetics, to closely associate a particular rule with the applicable enforcement mechanism. Foods are not covered under the rules, because there currently are no data indicating a need for CR packaging of food products.

Current FHSA regulations partially exempt small packages, minor hazards, and certain special circumstances from the FHSA's labeling requirements. 16 CFR 1500.83(a). Writing markers and ballpoint pens are exempt from full cautionary labeling requirements relating to toxicity if

they meet specifications listed in the regulations. These products are also excluded from the child-resistant packaging requirements in this final rule due to the difficulty a child would have in obtaining a toxic amount of fluid from these types of products. For the same reason, products that are packaged so their contents are not free-flowing, such as some battery terminal cleaners, paint markers, and make-up removal pads, are also excluded from the child-resistant packaging requirements of the final rules.

E. Statutory Considerations

1. Hazard to Children

Before issuing rules requiring CR packaging, the Commission must find that the degree or nature of the hazard to children in the availability of the products in question by reason of their packaging is such that special packaging is required to protect children from serious injury or illness from handling, using, or ingesting the products. 15 U.S.C. 1472(a)(1). The Commission made these findings preliminarily with regard to household chemicals and cosmetics in the preambles to the ANPR and NPR for the rules

that are being issued in final form today.[3] Subsequent CPSC staff review of additional data on mineral oil-based cosmetics, as discussed above, validate that children access these products and that those that contain 10 percent or more hydrocarbons with viscosities under 100 SUS at 100 °F can result in serious injury. In fact, it is worth noting that several brands of baby oil, a product obviously intended for use on small children, are labeled with a warning as follows:

> For external use only. Keep out of children's reach to avoid drinking and accidental inhalation, which can cause serious injury. Should breathing problems occur, consult a doctor immediately.

That warning is in effect the required PPPA statutory finding.

With respect to the general category of hydrocarbon-containing products, Congress, in enacting the original PPPA in 1970, specifically addressed the hazard of ingesting and

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[3] See 62 FR 8661-2 (February 26, 1997) and 65 FR 98-9 (January 3, 2000), which are hereby incorporated by reference.

It is also worth noting that the PPPA "hazard to children" finding with respect to these hydrocarbons has also been made as a prerequisite to issuing the three current child-resistant packaging regulations that address specific household products containing hydrocarbons: prepackaged liquid kindling and illuminating preparations, (e.g., lighter fluid), 16 CFR 1700.14(a)(7); prepackaged solvents for paint or other similar surface coating materials (e.g., paint thinners), 16 CFR 1700.14(a)(15); and nonemulsion liquid furniture polish (16 CFR 1700.14(a)(2).

aspirating hydrocarbon-containing products as one of the fundamental bases of the need for the PPPA:

> In the household specialties area, some chemicals cause serious illness requiring lengthy hospitalization from which the child may never recover. ... On ingestion, these petroleum distillates [hydrocarbons] are readily aspirated into the lungs and may lead to severe chemical pneumonitis in a matter of minutes.

H.R. Rep. No. 91-1642 at 5 (1970).

For the foregoing reasons, the Commission finds that the degree or nature of the hazard to children in the availability of products that contain 10 percent or more hydrocarbons with viscosities under 100 SUS at 100 °F, by reason of their packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the products.

2. Technical Feasibility, Practicability, and Appropriateness

As a prerequisite to CR packaging rules, the Commission must also find that the special packaging is "technically feasible, practicable, and appropriate." 15 U.S.C. 1472(a)(2). Technical feasibility may be found when technology exists or can be readily developed and implemented by the effective date to produce packaging that

conforms to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use. *See* S. Rep. No. 91-845, at 10 (1970).

The Commission made these findings preliminarily and issued the proposed rules. Those findings, which appear at 65 FR 99-100, are hereby incorporated by reference. No comments were received in response to the NPR regarding the technical aspects of child-resistant packaging. Therefore, the Commission concludes that CR packaging is technically feasible, practicable, and appropriate for products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F.

3. *Other Considerations*

Section 3(b) of the PPPA requires that the Commission consider the following in establishing special packaging standards:

a. The reasonableness of the standard;

b. Available scientific, medical, and engineering data concerning special packaging and concerning childhood

accidental ingestions, illness, and injury caused by household substances;

c. The manufacturing practices of industries affected by the PPPA; and

d. The nature and use of the household substance.

15 U.S.C. 1472(b).

The Commission has considered these factors with respect to the various determinations made in this rulemaking, and finds no reason to conclude that the rules are unreasonable or otherwise inappropriate.

F. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year after the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n. The NPR proposed an effective date of one (1) year after publication of the final rules.

Two comments received on the NPR requested additional time for companies that may need it. However, no information was submitted to demonstrate that more than one year would be necessary to adopt child-resistant packaging for any product.

The CPSC staff estimated that any necessary packaging changes could be achieved during a one-year time frame. Therefore, the Commission is issuing these final rules with an effective date of one year after the date of their publication in the Federal Register. The Commission is not establishing a general procedure for stays of enforcement of the requirements of these final rules. However, there is nothing to preclude an individual company from requesting relief from the CPSC Office of Compliance if specific difficulties arise in complying by the effective date.

G. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the RFA provides that an agency is not required to prepare a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared an assessment of the impact of rules to require CR packaging for products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F. A copy of the assessment is available for inspection in the docket for this rulemaking. The assessment reports that the incremental cost of providing basic CR packaging is usually small ($0.005-$0.02/per package), and confirms the staff's previous experience with child-resistant packaging and current packaging. Child-resistant packaging is widely available and the incremental costs are small relative to the cost of most household chemicals and cosmetic products. In addition, the one (1) year effective date should include enough lead-time for companies to use up existing package inventory.

Based on that assessment, the Commission certified in the NPR that the rules, if promulgated as proposed, would not have a significant economic effect on a substantial number of small entities.

The NPR was sent to 375 trade associations and companies believed to make products that contain hydrocarbons. The Commission did not receive any comments in response that questioned the certification. Therefore,

there is no evidence available that the rules would have a significant economic impact on a substantial number of small entities.

Based on the foregoing analysis, the Commission certifies that these final rules do not have a significant impact on a substantial number of small businesses or other small entities.

H. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has analyzed the possible environmental effects associated with the proposed PPPA requirements on products that contain 10 percent hydrocarbons or more by weight and have a viscosity less than 100 SUS at 100°F.

The Commission's regulations state that rules requiring special packaging normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). Nothing in these rules alters that expectation. Therefore, because the rules would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

I. Executive Order No. 12988

As provided in Executive Order No. 12988 the CPSC states the preemptive effect of these final rules as follows.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, "no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard." 15 U.S.C. 1476(a). A State or local standard may be excepted from this preemptive effect if (1) the State or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the State or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through procedures specified at 16 CFR part 1061. 15 U.S.C. 1476(c)(1). In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a

household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, these rules preempt non-identical state or local special packaging standards for such drug products.

List of Subjects in 16 CFR Part 1700.

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Reporting and record keeping requirements.

For the reasons stated in the preamble, the Commission amends 16 CFR 1700.14(a) as follows.

Part 1700-POISON PREVENTION PACKAGING ACT OF 1970 REGULATIONS

1. The authority citation for part 1700 continues to read as follows:

Authority: 15 U.S.C. 1471-1476. Secs. 1700.1 and 1700.14 also issued under 15 U.S.C. 2079(a).

2. In § 1700.14(a), add new paragraph (31) to read as follows:

(31) Hazardous substances containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are hazardous substances as defined in the Federal Hazardous Substances Act (FHSA) (15

U.S.C. 1261(f)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols, or pump- or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Writing markers and ballpoint pens exempted from labeling requirements under the FHSA by 16 CFR 1500.83.

(iii) Products from which the liquid cannot flow freely, including but not limited to paint markers and battery terminal cleaners.

For purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

3. In § 1700.14(a), add new paragraph (32) to read as follows:

(32) Drugs and cosmetics containing low-viscosity hydrocarbons. All prepackaged nonemulsion-type liquid household chemical products that are drugs or cosmetics as defined in the Federal Food, Drug, and Cosmetics Act (FDCA) (21 U.S.C. 321(a)), and that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F, shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c), except for the following:

(i) Products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., aerosols, or pump- or trigger-actuated sprays where the pump or trigger mechanism has either a child-resistant or permanent attachment to the package).

(ii) Products from which the liquid cannot flow freely, including but not limited to makeup removal pads.

For the purposes of this requirement, hydrocarbons are defined as substances that consist solely of carbon and

hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbons in the product is the sum of the percentages by weight of the individual hydrocarbon components.

Dated: _____, 2001.

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Todd A. Stevenson, Acting Secretary
Consumer Product Safety Commission

DRAFT

List of Relevant Documents

1. Briefing memorandum from Suzanne Barone, Ph.D., EH, to the Commission, "Final Rule to Require Special Packaging for Hydrocarbons of Low Viscosity," September __, 2001.

2. Memorandum from Robert L. Franklin, EC to Suzanne Barone, Ph.D., EH, "Economic Considerations Regarding the Final Rule to Require CR Packaging for Products Containing Low Viscosity Hydrocarbons," August 24, 2001.

3. "Pediatric Potential Aspirations of Cosmetic Products: 1998 Data," C. Craig Morris, Ph.D., U.S. Consumer Product Safety Commission, Directorate for Epidemiology, Division of Hazard Analysis, March 2001.

4. "Pediatric Hydrocarbon Exposures and Potential Aspirations," C. Craig Morris, Ph.D., U.S. Consumer Product Safety Commission, Directorate for Epidemiology, Division of Hazard Analysis, February 2001.